



10012279



intensive and  
critical care  
medicine



THE **MEDICINES** COMPANY®

Received SEC  
MAY 12 2010  
Washington, DC 20549

## company profile

The Medicines Company is focused on advancing the treatment of intensive and critical care patients through the delivery of innovative, cost-effective medicines to the worldwide hospital marketplace. We market Angiomax® (bivalirudin) for injection in the United States and other countries for use in patients undergoing coronary angioplasty, and Cleviprex® (clevidipine butyrate) injectable emulsion in the United States for the reduction of blood pressure when oral therapy is not feasible or not desirable. We have two products in late stage development, cangrelor, an investigational antiplatelet agent and oritavancin, a semi-synthetic lipoglycopeptide antibiotic. Our pipeline also includes a serine protease inhibitor, CU2010, in early-stage development for potential in surgical blood loss. In September 2009, we entered into a license agreement with Eagle Pharmaceuticals, Inc. under which we will have rights in the United States and Canada to a ready-to-use formulation of Argatroban, which is currently under review by the U.S. Food and Drug Administration. Argatroban is an anticoagulant for prophylaxis or treatment of thrombosis in patients with or at risk for heparin-induced thrombocytopenia (HIT), and for patients with or at risk for HIT undergoing percutaneous coronary intervention (PCI). In late December 2009, we acquired ApoA-I Milano. ApoA-I Milano is a naturally occurring variant of a protein found in human high-density lipoprotein (HDL) that has the potential to reverse atherosclerotic plaque development and reduce the risk of coronary events in patients with acute coronary syndrome (ACS).

Portfolio	Pre-Clinical	I	II	III	Approval	Market
<b>ANGIOMAX®</b> (bivalirudin) for injection						
PCI						
PCI-HITTS						
ACS*						
Cardiac Surgery (including HITTS)†						
Carotid Procedures						
Pediatrics‡						
Cardiac Surgery—Canada‡						
<b>ANGIOX®</b> (bivalirudin)						
ACS—EU						
<b>CLEVIPREX®</b> (clevidipine butyrate) injectable emulsion						
Acute Hypertension—US						
Acute Hypertension—EU						
<b>CANGRELOR</b>						
PCI						
ACS						
BRIDGE to Surgery						
<b>CU2010</b> (surgical blood loss)						
Cardiac Surgery						
Other Major Surgery						
<b>ORITAVANCIN</b>						
Acute Bacterial Skin and Skin Structure Infections (ABSSSI)§						
Bacteremia						
Anthrax						
c. difficile-associated diseases						
<b>ARGATROBAN</b>						
Argatroban Ready to Use Formulation**						
<b>APOA-I MILANO</b>						
ACS/Atherosclerosis						

\* The FDA issued a not approvable letter

† The FDA has granted an additional six months of pediatric exclusivity for Angiomax® (bivalirudin) and will not authorize commercialization of generic versions of bivalirudin prior to September 2010

‡ Canadian approval for cardiac surgery is limited to HITTS patients

§ In August of 2009, The Medicines Company withdrew the European MAA

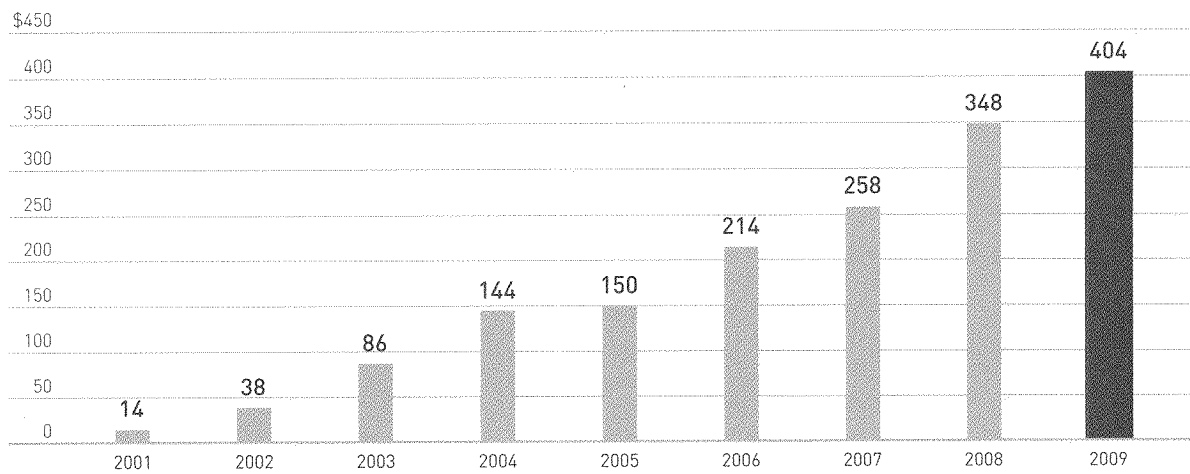
\*\* Argatroban rights are in the U.S. and Canada only

## financial overview

BALANCE SHEET DATA (in thousands)	December 31,	
	2009	2008
Cash and cash equivalents, available for sale securities and accrued interest receivable	\$177,113	\$217,542
Total assets	\$374,776	\$387,404
Total liabilities	\$134,387	\$ 89,379
Total stockholders' equity	\$240,389	\$298,025
Working capital	\$156,103	\$212,222

Derived from audited financials

## revenues [\$ in millions]



## 2009 highlights

- Acquired Targanta Therapeutics Corporation
- Received acceptance of the Cleviprex application in Europe
- Received 6-month pediatric exclusivity for Angiomax in the U.S.
- Published HORIZONS-AMI Trial One-Year Results in *The Lancet*
- Received two new U.S. patents for Angiomax, both are listed in the Orange Book
- Reported positive interim data from ACCELERATE for Cleviprex in patients with acute hypertension and intracerebral hemorrhage
- Discontinued trials, then reported full data for cangrelor at AHA; simultaneous publication of two NEJM papers on the CHAMPION PCI and PLATFORM trials
- Received approval for Angiox® (bivalirudin) in STEMI patients undergoing PCI
- Licensed global rights to ApoA-I Milano

# dear shareholders:

We help our customers to improve patient care by delivering innovative medicines to treat intensive and critical care patients in hospitals worldwide. More than ever today, these hospitals need new products and new ways of working to improve patient outcomes and the economics of care.

Our global net revenues exceeded \$400 million for the first time in 2009, and we estimate that approximately 580,000 patients worldwide were given Angiomax/Angiox to reduce their risk of thrombosis and bleeding during potentially lifesaving coronary angioplasty procedures. In the U.S., Angiomax is now the leading injectable blood thinner used in these procedures. In Europe, where the product is called Angiox, we successfully gained regulatory approval for use in emergency coronary angioplasty for patients with major heart attacks. These advances were built on a foundation of clinical research data published in 2008–2009 that demonstrated immediate benefit and a 41% relative risk reduction in cardiac-related death two years after treatment. This result establishes Angiomax/Angiox as a global standard in modern heart attack treatment. Such innovation is all the more valuable to our customers because it can be associated with significant cost savings.

Real improvements in clinical outcomes and simultaneous cost savings like these are, we believe, a recipe for success in hospital medicine. But such innovation does not come easily. During 2009 we faced challenges as our customers experienced severe economic constraints resulting in service line reductions and cost cutting. The launch of Cleviprex, our injectable product for control of severely high blood pressure in hospital, has been disappointingly slow. Despite excellent clinical data, which enabled the U.S. FDA to approve the drug with a broad label, we were unable to convince our cash-strapped customers that the product reduces cost of care. We are working to rectify this and—encouraged by experts in the field of neurocritical care, heart, and vascular surgery—believe we can provide compelling evidence of the value of tight blood pressure control in intracranial hemorrhage, occlusive stroke treated with clot busters, coronary-artery bypass and valve surgery, and major vascular procedures such as repair of aortic aneurisms. All told, these conditions, which require emergency and intensive care, are reported in more than 350,000 patients per year in the U.S. alone. We are confident that the product represents a significant innovation for our customers and a valuable asset in our portfolio. Therefore in spite of recent manufacturing quality problems at our supplier, we plan to continue investing aggressively in Cleviprex worldwide because we believe in its potential.

Over the last five years, funded by our own cash flow, we have built a leading portfolio of intensive and critical care development compounds through licensing and acquisition. Our two leading candidates, cangrelor and oritavancin are in Phase 3 clinical development with anticipated global regulatory filings within the next three years. Clinical results for cangrelor in acute coronary syndrome (ACS) patients undergoing coronary angioplasty failed to meet Phase 3 objectives in 2009. However, the data showed ample evidence of pharmacological effect, and clinical results showed significant reductions in secondary combined endpoints including death, major heart attack, stent thrombosis and urgent revascularization. We are encouraged by these results and plan for Phase 3 studies to continue. There is a clear medical and economic need for an injectable, fast onset and rapidly reversible

platelet inhibitor for use in hospitals. We also expect oritavancin Phase 3 trials in acute bacterial skin and skin structure infection to begin shortly. The unique dosing profile of this compound is expected to provide excellent outcomes and reduced overall treatment costs in certain resistant hospital skin infections such as MRSA. Down the road, we also believe oritavancin can provide a new treatment option in the potentially deadly gut infections caused by *Clostridium difficile*.

We added two valuable assets to our portfolio this year. Our licensing deal for ApoA-I Milano provides us with the opportunity to attack the massive global problem of vulnerable coronary, cerebral and peripheral plaque associated with high cholesterol. If ApoA-I Milano demonstrates the same level of effectiveness in larger trials as was seen in the first human study, we may anticipate clinical and economic outcome improvements of great importance. We also in-licensed rights to a ready-to-use form of Argatroban, which has been filed with the FDA. Argatroban is an intravenous drug used to treat patients with dangerous heparin reactions called HIT/TS. We believe our Argatroban will improve hospital economics for treating these patients.

Other products in our broad development portfolio also progressed. We moved CU2010 forward in human safety studies and successfully identified other plasmin and kallikrein inhibitors that may have utility in preventing blood loss and reducing transfusions in open heart surgery patients. Managing such severe blood loss is medically challenging and costly.

We face real business challenges at present, including potential premature expiry of the Angiomax exclusivity in the U.S. in late 2010. We have taken steps to restore our rights to composition of matter exclusivity until late 2014. We have secured new U.S. patents covering Angiomax which run to 2028 and we intend to defend this valuable intellectual property vigorously. In Europe, where we continue to invest in clinical trials of Angiox, our market exclusivity is already protected until late 2015.

Looking ahead, in addition to developing a leading portfolio, we are building a global organization that can meet the needs of around 2,600 leading hospitals that deliver more than 80% of intensive and critical care worldwide. This means operating in 25 countries of North America, Central and Eastern Europe, Latin America and Asia. We are today working in 16 countries and planning operation expansion for the remainder, while staying tight on operating expenses.

As ever, we are grateful to our customers, shareholders, partners and employees for their dedication to the mission of saving lives and improving the health of patients with heart attacks, vascular disease, strokes and serious infections.

We look forward to growth in 2010 and beyond.

Sincerely,



Clive Meanwell  
Chairman and Chief Executive Officer



Glenn Sblendorio  
Executive Vice President and Chief Financial Officer

## ANGIOMAX®/ANGIOX® (bivalirudin)

Angiomax/Angiox (bivalirudin) is a direct thrombin inhibitor used as an anticoagulant in patients undergoing percutaneous coronary intervention (PCI) for treatment of acute coronary syndrome (ACS). ACS is a disease state that includes unstable angina, non-ST segment elevation myocardial infarction (NSTEMI) and ST-segment elevation myocardial infarction (STEMI). PCI, a minimally invasive procedure used to open narrowed or blocked coronary arteries in ACS patients is one of the most frequently performed therapeutic procedures globally. Anticoagulation is necessary to perform PCI safely by preventing the formation of blood clots during the procedure, and Angiomax has leading market share in the U.S. in PCI patients. The product is also approved in Europe, Canada, Israel, Australia, New Zealand, and many countries in Middle and South America. Incidence and prevalence of ACS continue to rise in the U.S., Europe, and emerging markets, worldwide. Accordingly, the need for effective therapies that improve patient outcomes while reducing the risk of complication is also increasing globally.

The HORIZONS AMI trial was the first drug trial to demonstrate a mortality benefit in STEMI patients. In 2009, one-year data from the HORIZONS AMI trial were published in *The Lancet*, and the late-breaking two-year results were presented at the Transcatheter Cardiovascular Therapeutics Conference (TCT). The two-year data show that use of Angiomax versus heparin and a glycoprotein IIb/IIIa inhibitor in primary PCI resulted in a relative risk reduction (RRR) for cardiac-related death of 41%, and for all-cause death by 25%. The RRR for major bleeding was 36% while major adverse cardiac events and stent thrombosis were comparable between the two groups. Based on these compelling data, Angiox was approved in Europe for use in STEMI patients as well, making Angiox the only anticoagulant authorized in Europe for use in adults across the full spectrum of risk of ACS. Angiomax also received a Class 1B rating in the current ACC/AHA STEMI guidelines.

An important milestone for Angiomax was that the FDA granted additional six months of pediatric exclusivity. Angiomax was studied in this population due to the critical need for safe and effective anticoagulant treatments for children undergoing intravascular coronary procedures.

This year, we partnered with the largest and most comprehensive observational U.S. hospital drug utilization and financial database. It includes more than 500 acute care facilities and approximately 82 million patient records, representing all geographical areas, a broad range of bed sizes, teaching and non-teaching, and urban and rural facilities. The database was queried to test the "real world" translation of the positive clinical trial results for Angiomax/Angiox. Consistent with our clinical trial results, data collected on over 450,000 patients has confirmed that Angiomax patients undergoing PCI had significantly reduced in-hospital bleeding, mortality, length of stay and total costs compared to patients treated with heparin and glycoprotein IIb/IIIa inhibitors.



## CLEVIPREX® (clevidipine butyrate) injectable emulsion

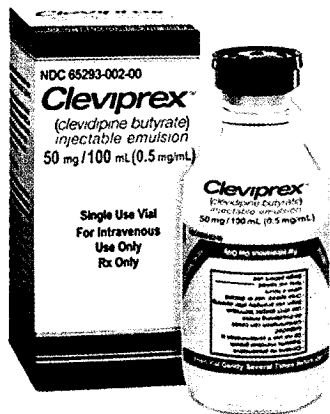
Cleviprex (clevidipine butyrate) is an injectable dihydropyridine calcium channel blocker indicated for the reduction of blood pressure when oral therapy is not feasible or not desirable. Acute severe elevations in blood pressure can be fatal and affected patients require rapid and precisely adjustable blood pressure control. Cleviprex offers a rapid onset of activity (2 to 4 minutes), rapid offset of activity (full offset of activity in 5 to 15 minutes), and a short half-life (about 1 minute). Cleviprex can be titrated for predictable BP control. Unlike many current antihypertensive treatments that are metabolized by the kidney or liver, Cleviprex is metabolized by esterases in the blood and extravascular tissues and does not accumulate in the body.

Since the U.S. approval by the FDA in 2008, 425 hospitals have added Cleviprex to their formulary and approximately 21,000 patients were treated through 2009. An interim analysis of the ACCELERATE trial was presented in November at the Annual Meeting of the Neurocritical Care Society.

- Reduction to target systolic blood pressure ( $\leq 160$ mmHg) was achieved in 100% of patients within 30 minutes (N=30);
- 97% of patients reached target with Cleviprex monotherapy within initial 30 minutes;
- Median time to target systolic blood pressure was 6.5 minutes;
- There were no instances of hypotension in the initial 30-minute period of Cleviprex therapy.

In March our Marketing Authorization Application (MAA) for Cleviprex was accepted for review in the European Union, and the submissions filed in 2008 for Australia, Canada and Switzerland remain under regulatory review. In New Zealand, Cleviprex received regulatory approval in July.

We voluntarily recalled manufactured lots of Cleviprex due to the potential presence of visible particulate matter which has been observed in some vials during a routine annual inspection. The visible particulate matter is primarily made up of sub-visible inert stainless steel particles of around 2.5 microns in diameter. Experimental animal and human data indicate that these particles are scavenged by macrophages and other cells of the reticuloendothelial system. Particles could theoretically reduce blood flow in capillaries, cause mechanical damage to some tissues, or initiate acute or chronic inflammatory reactions. Reduced blood supply to tissues may lead to ischemia or organ insufficiency in the brain, kidney, liver, heart or lungs.





**THE MEDICINES COMPANY®**

May 11, 2010

**VIA OVERNIGHT MAIL**  
Securities and Exchange Commission  
100 F Street, NE  
Washington, DC 20549

**SEC  
Mail Processing  
Section**

**MAY 12 2010**

**Washington, DC  
107**

Re: The Medicines Company  
Commission File No. 000-31191  
Annual Report to Stockholders

Ladies and Gentlemen:

On behalf of The Medicines Company (the "Company"), and in accordance with the requirements of Rule 14a-3(c) under the Securities Exchange Act of 1934, as amended, enclosed are seven paper copies of the Company's annual report to stockholders for the fiscal year ended December 31, 2009. The Company began mailing the annual report to stockholders along with its definitive proxy materials to its stockholders on or about May 7, 2010.

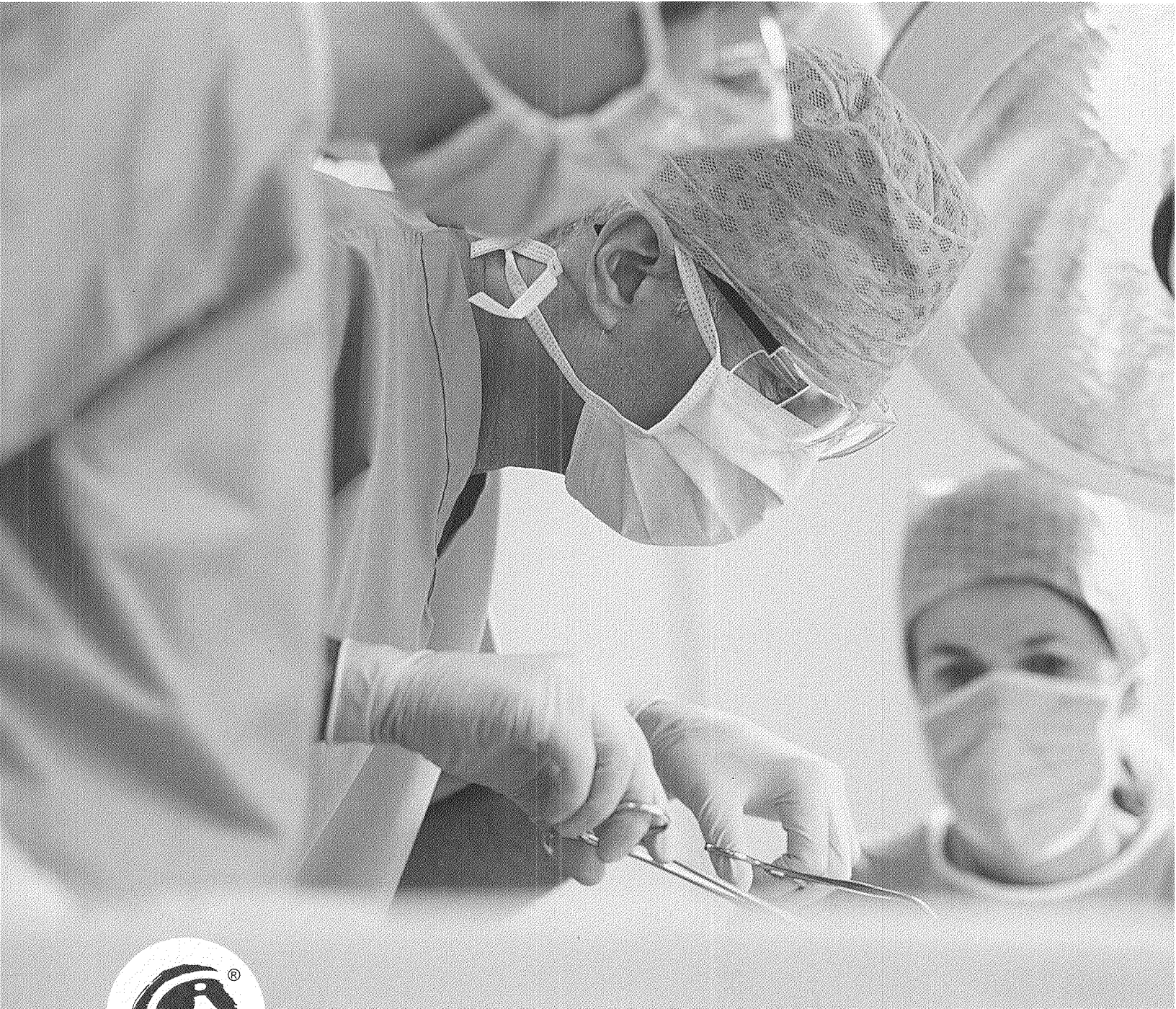
Please acknowledge receipt of the enclosed materials by stamping the enclosed receipt copy of this letter and returning it to the undersigned in the enclosed envelope.

Please call the undersigned if you have any questions regarding this matter.

Very truly yours,

Stephen M. Rodin  
Deputy General Counsel

Enclosures



“Patient’s lives have been saved because of the tight blood pressure control which can only be achieved with clevidipine, and cannot be achieved with any other IV antihypertensive drugs.”

Dr. Tariq M. Janjua Medical Director, Neurocritical Care, St. Joseph’s Hospital





## CANGRELOR

Cangrelor is an investigational injectable platelet P2Y<sub>12</sub> receptor inhibitor with ideal attributes for use in the acute care setting: potent anti-platelet effect, instant onset, very rapid reversibility, with the potential of allowing a smooth transition to oral agents after PCI.

In 2009, we completed a large Phase 3 program called CHAMPION which was designed to assess the hypothesis that maximal inhibition of platelet activation with cangrelor during PCI, at the time of greatest thrombotic risk, will improve short-term outcomes as compared to oral administration of 600 mg of clopidogrel. The program had enrolled nearly 14,000 patients when it was discontinued in May after the Interim Analysis Review Committee reported to the Company that one of the two trials, CHAMPION-PLATFORM, would not meet the goal of demonstrating persuasive evidence of clinical

## ORITAVANCIN

Oritavancin is an investigational lipoglycopeptide antibiotic with potent and rapid bactericidal (killing) activity against a broad spectrum of gram-positive bacteria, including methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant enterococcus (VRE).

As bacteria become more resistant to the current generation of marketed antibiotics, there is a growing threat of prolonged illness and hospitalization, increased mortality rates and increased hospital and health system costs<sup>1</sup>. For example, a recent government study found that 59% of hospitalizations due to skin infections were attributable to MRSA<sup>2</sup>. Further, the incidence of VRE is also increasing with one study at a large academic medical center finding an increase in the proportion of VRE in enterococcus isolates to 30% from 17% over a 10-year period.<sup>3</sup>

In addition to the increasing resistance of bacteria to existing antibiotics, other shortcomings of current therapies include the need for prolonged

## CU2010

CU2010 is an investigational serine protease inhibitor that acts as a hemostasis modulator designed to attenuate complications of major surgery.

Coronary artery bypass graft (CABG) surgery has become a routine procedure that is performed in approximately 1 million patients annually worldwide. The use of a cardiopulmonary bypass often triggers activation of the coagulation system and evokes systemic inflammatory responses that may result in excessive bleeding and other postoperative complications.

## APoA-I MILANO

In December, we obtained an exclusive worldwide license to ApoA-I Milano, an investigational product. ApoA-I Milano is a naturally occurring variant of a protein found in human high-density lipoprotein (HDL) that has the potential to reverse atherosclerotic plaque development and reduce the risk of coronary events in patients with ACS. Complications of coronary artery disease (CAD) remain the leading cause of death worldwide.<sup>1</sup> Current therapeutic options to modify the atherosclerotic disease process in patients with ACS are invasive. There is a significant opportunity for a disease-modifying drug.

## ARGATROBAN Ready to Use Formulation

In September 2009, we licensed the rights in the U.S. and Canada to a ready-to-use formulation of Argatroban which is currently under review by the U.S. Food and Drug Administration.

effectiveness that could form the basis for regulatory approval and that the CHAMPION-PCI trial showed no significant differences in measures of clinical effectiveness.

In November 2009, the results of both trials were published in two *New England Journal of Medicine* papers and presented at American Heart Association Scientific Session 2009 as Late Breaking Clinical Trials. The primary endpoint of 48-hour death, myocardial infarction and ischemia driven revascularization was not met. However, analysis of the combined data from PLATFORM and PCI showed marked effects on planned secondary endpoints. For example, the 48-hour hazard of death, Q-wave myocardial infarction or ischemia-driven revascularization was reduced by 39% (p-value 0.005) and that of death, Q-wave MI or acute stent thrombosis was reduced by 45% (p-value 0.003).

Currently, we are continuing to collect one-year follow-up data for mortality of patients treated in CHAMPION and we are enrolling patients into the BRIDGE trial, a study designed to assess the use of prolonged cangrelor infusion as a platelet inhibiting bridge for patients who discontinue clopidogrel before cardiac surgery.

courses of treatment, required drug level and/or toxicity monitoring, and various side effects and tolerability concerns. We are developing an IV formulation of oritavancin for the treatment of acute bacterial skin and skin structure infections (ABSSSI), to be administered as a single dose treatment. Due to the upfront delivery of oritavancin, it has the potential to leverage the pharmacokinetic/pharmacodynamic properties of the product to achieve optimized early tissue penetration and bactericidal effects. A single administration is also expected to ensure compliance, may facilitate earlier patient discharges, and potentially avoid admissions for certain patients altogether by allowing treatment in an outpatient or non-hospital setting. Oritavancin has been well tolerated in clinical trials to date, with a lower rate of adverse events than vancomycin, and has not required monitoring of blood count or for hepatic or renal insufficiency.

Oritavancin will also be evaluated for a range of other IV indications, such as bacteremia, anthrax, and implant infections, and there are also plans for the development of an oral delivery of oritavancin for the treatment of *Clostridium difficile* (*c. difficile*) infections. Similar to MRSA and VRE, *c. difficile* infections also pose a growing challenge to the healthcare system. There were an estimated 500,000 cases in the U.S. in 2008 with that number growing at a rate of 10% per year, and relapse rates on existing drugs are greater than 20%.<sup>4</sup> In preclinical models to date, oritavancin has demonstrated efficacy against *c. difficile*, while also inhibiting spore outgrowth, offering the potential to both effectively treat *c. difficile* infections and reduce the risk of relapse.

<sup>1</sup> Shorr, Andrew F. Epidemiology and Economic Impact of Methicillin-Resistant Staphylococcal aureus. *Pharmacoeconomics*. 2007; 25 (9): 751-768

<sup>2</sup> Edelsberg J, Taneja C, Zervos M, et al. Trends in U.S. Hospital Admissions for Skin and Soft Tissue Infections. *Emerg Infect Dis* Sep 2009 (preprint)

<sup>3</sup> Eliopoulos GM. Microbiology of drugs for treating multiply drug-resistant Gram-positive bacteria. *Infec* 2009; 59 Suppl 1:S17-24

<sup>4</sup> Williams OM and Spencer RC. The management of *Clostridium difficile* infection. *Br Med Bull* 2009; 91(1):87-110

Therefore, patients undergoing cardiac surgery receive approximately one fifth of all red-cell transfusions, and each unit transfused is known to increase the risk of infection.<sup>1</sup> We believe that multi-modal intervention with various enzymatic mediators of hemostasis can reduce blood loss and have a protective effect on procedure—and transfusion-related organ damage.

CU2010 has a unique profile that provides the potential to modulate procedure-related hemostasis derangements. In 2009 we initiated a Phase 1 trial in healthy volunteers. This double-blind, placebo-controlled study was designed to assess safety and tolerability of escalating doses of CU2010 in healthy subjects. It was also aimed at characterizing the pharmacokinetics and at investigating functional pharmacodynamics.

<sup>1</sup> Stover *et al.* (1998) *Anesthesiology*; Chelemer *et al.* (2002) *Ann. Thorac. Surg.*

ApoA-I Milano was discovered in Italy when approximately 45 individuals were identified in the small village Limone sul Garda in northern Italy. They all had high cholesterol levels but low incidence of cardiovascular disease and they all had ApoA-I Milano. In multiple non-clinical models, ApoA-I Milano rapidly removed excess cholesterol from artery walls, thereby stabilizing and regressing atherosclerotic plaque. A Phase 2 study in 36 patients with ACS demonstrated statistically significant reductions in coronary plaque volume by 4.2%, as well as a significant decrease in the percent plaque volume, after administration of five doses of ApoA-I Milano at weekly intervals. These findings were published in the *Journal of the American Medical Association* and continue to be widely referenced and discussed.

ApoA-I Milano is a good strategic fit with our focus and development capabilities. We expect to be able to leverage our relationships in the cath lab with interventional cardiologists as well as our knowledge and resources in the areas of manufacturing, clinical development and regulatory to develop this product.

<sup>1</sup> Murray CJL, Lopez AD, eds. *The Global Burden of Disease*: Boston, Mass: Harvard School of Public Health 1996

Argatroban, currently marketed in a concentrated formulation, is approved as an anticoagulant for prophylaxis or treatment of thrombosis in patients with or at risk for heparin-induced thrombocytopenia (HIT), and for patients with or at risk for HIT undergoing percutaneous coronary intervention (PCI).

The ready-to-use product has the potential to reduce waste and workload and increase patient safety by decreasing dispensing errors.

## corporate information

### Employees

462 (as of February 15, 2010)

### Global Center

8 Sylvan Way  
Parsippany, NJ 07054

### Founded

1996

### IPO

2000

### Stock Listing

Nasdaq: MDCO

### Transfer Agent

American Stock Transfer & Trust Company

### Independent Auditors

Ernst & Young LLP

### Corporate Counsel

Wilmer Cutler Pickering Hale and Dorr, LLP

### Investor Relations Contact

Michael Mitchell  
973-290-6000  
investorrelations@themedco.com

### Stock Information

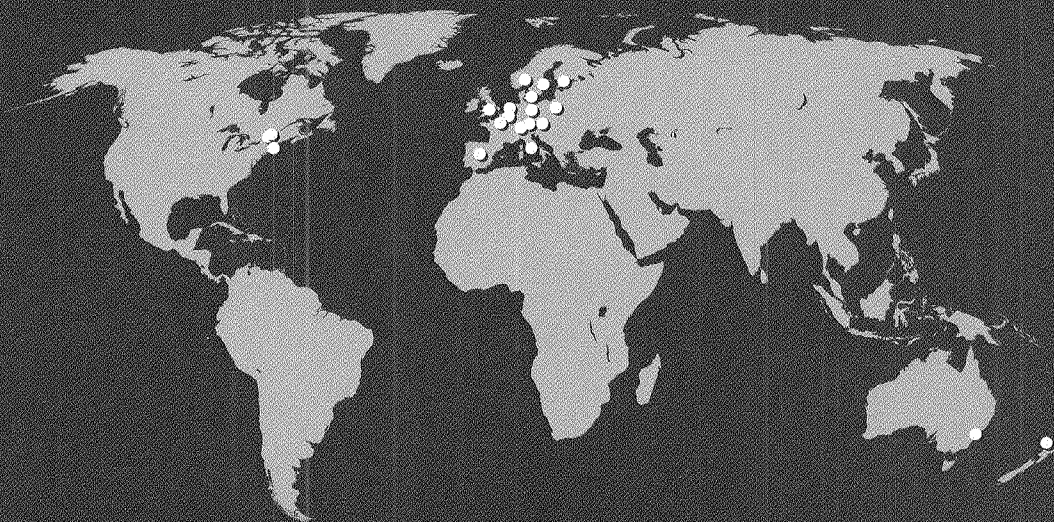
The following table reflects the range of the high and low bid information per share of our common stock, as reported on the Nasdaq Global Select Market for the periods indicated. These prices reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

Year Ended December 31, 2008	High	Low
First Quarter	\$21.41	\$16.38
Second Quarter	\$21.13	\$17.18
Third Quarter	\$28.00	\$19.07
Fourth Quarter	\$24.18	\$11.37
Year Ended December 31, 2009	High	Low
First Quarter	\$16.77	\$ 8.73
Second Quarter	\$11.50	\$ 6.15
Third Quarter	\$12.12	\$ 7.36
Fourth Quarter	\$11.24	\$ 7.00

Statements contained in this document about The Medicines Company that are not purely historical, and all other statements that are not purely historical, may be deemed to be forward-looking statements for purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995. Without limiting the foregoing, the words "believes," "anticipates" and "expects" and similar expressions are intended to identify forward-looking statements. These forward-looking statements involve known and unknown risks and uncertainties that may cause our actual results, levels of activity, performance or achievements to be materially different from those expressed or implied by these forward-looking statements. Important factors that may cause or contribute to such differences include whether our products will advance in the clinical trials process on a timely basis or at all, whether clinical trial results will warrant submission of applications for regulatory approval, whether we will be able to obtain regulatory approvals, whether physicians, patients and other key decision-makers will accept clinical trial results, and such other factors as are set forth in the risk factors detailed from time to time in our periodic reports and registration statements filed with the Securities and Exchange Commission including, without limitation, the risk factors detailed in our Annual Report on Form 10-K filed on March 16, 2010, which are incorporated herein by reference. We specifically disclaim any obligation to update these forward-looking statements.

## offices

Parsippany, NJ  
Waltham, MA  
Oxford, England  
Paris, France  
Munich, Germany  
Leipzig, Germany  
Rome, Italy  
Montreal, Quebec  
St. Laurent, Quebec  
Zurich, Switzerland  
Stockholm, Sweden  
Warsaw, Poland  
Copenhagen, Denmark  
Vienna, Austria  
Belgium, Brussels  
Amsterdam, Netherlands  
Auckland, New Zealand  
Sydney, Australia  
Oslo, Norway  
Helsinki, Finland



#### OFFICERS

**Clive Meanwell, M.D.**  
Chairman and Chief Executive Officer  
(Director)

**Glenn Sblendorio**  
Executive Vice President and  
Chief Financial Officer

**Paul Antinori**  
Senior Vice President and  
General Counsel

**William O'Connor**  
Chief Accounting Officer

**Leslie C. Rohrbacker**  
Vice President,  
Chief Human Strategy Officer

#### DIRECTORS

**William W. Crouse**  
Managing Director  
HealthCare Ventures

**Robert J. Hugin**  
President and Chief Operating Officer  
Celgene Corporation

**Armin M. Kessler**  
Former Chief Operating Officer and  
Head of Pharmaceutical Division  
Hoffmann-La Roche, Inc.

**Robert G. Savage**  
President and Owner  
Strategic Imagery LLC

**Melvin K. Spigelman, M.D.**  
President and Chief Executive Officer  
Global Alliance for TB Drug  
Development

**Elizabeth H.S. Wyatt**  
Former Vice President, Corporate  
Licensing  
Merck & Co., Inc.

**Hiroaki Shigeta**  
Former U.S. Head, Far East Relations  
Hoffman-La Roche, Inc.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended: December 31, 2009

Or

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number 000-31191

SEC Mail Processing Section

MAY 12 2010

Washington, DC 107



(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

04-3324394

(I.R.S. Employer Identification No.)

8 Sylvan Way

Parsippany, New Jersey

(Address of principal executive offices)

07054

(Zip Code)

Registrant's telephone number, including area code: (973) 290-6000

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class

Name of Each Exchange on Which Registered

Common Stock, \$.001 Par Value Per Share

NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [ ] No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes [ ] No [X]

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or Section 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [ ] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer [ ] Accelerated filer [X] Non-accelerated filer [ ] Smaller reporting company [ ] (Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes [ ] No [X]

The aggregate market value of voting Common Stock held by non-affiliates of the registrant on June 30, 2009 was approximately \$436,975,438 based on the last reported sale price of the Common Stock on the Nasdaq Global Select Market on June 30, 2009 of \$8.39 per share.

Number of shares of the registrant's class of Common Stock outstanding as of March 10, 2010: 53,006,903.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2009. Portions of the proxy statement are incorporated herein by reference into the following parts of the Form 10-K:

Part III, Item 10. Directors, Executive Officers and Corporate Governance;

Part III, Item 11. Executive Compensation;

Part III, Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters;

Part III, Item 13. Certain Relationships and Related Transactions, and Director Independence; and

Part III, Item 14. Principal Accountant Fees and Services.

**THE MEDICINES COMPANY**  
**ANNUAL REPORT ON FORM 10-K**  
**For the Fiscal Year Ended December 31, 2009**

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The Medicines Company® name and logo, Angiomax®, Angiox® and Cleviprex® are either registered trademarks or trademarks of The Medicines Company in the United States and/or other countries. All other trademarks, service marks or other tradenames appearing in this annual report on Form 10-K are the property of their respective owners. Except where otherwise indicated, or where the context may otherwise require, references to “Angiomax” in this annual report on Form 10-K mean Angiomax and Angiox, collectively. References to the “Company,” “we,” “us” or “our” mean The Medicines Company, a Delaware corporation, and its subsidiaries.

This annual report on Form 10-K includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. For this purpose, any statements contained herein regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management, other than statements of historical facts, are forward-looking statements. The words “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations expressed or implied in our forward-looking statements. There are a number of important factors that could cause actual results, levels of activity, performance or events to differ materially from those expressed or implied in the forward-looking statements we make. These important factors include our “critical accounting estimates” described in Item 7 in Part II of this annual report and the factors set forth under the caption “Risk Factors” in Item 1A in Part I of this annual report. Although we may elect to update forward-looking statements in the future, we specifically disclaim any obligation to do so, even if our estimates change, and readers should not rely on our forward-looking statements as representing our views as of any date subsequent to the date of this annual report.



## PART I

### Item 1. Business

#### Our Company

We are a global pharmaceutical company focused on advancing the treatment of critical care patients through the delivery of innovative, cost-effective medicines to the worldwide hospital marketplace. We have two marketed products, Angiomax® (bivalirudin) and Cleviprex® (clevidipine butyrate) injectable emulsion, and a pipeline of critical care hospital products in development, including two late-stage development product candidates, cangrelor and oritavancin, two early stage development product candidates, CU2010 and ApoA-I Milano, and marketing rights in the United States and Canada to a ready-to-use formulation of Argatroban for which a new drug application, or NDA, has been submitted to the U.S. Food and Drug Administration, or FDA. We believe that Angiomax, Cleviprex and our products in development possess favorable attributes that competitive products do not provide, can satisfy unmet medical needs in the critical care hospital product market and offer, or, in the case of our products in development, have the potential to offer, improved performance to hospital businesses.

The following chart identifies each of our marketed products and our products in development, their stage of development, their mechanism of action and the indications which they address or are intended to address. Each of our marketed products and products in development are administered intravenously.

<u>Product or Product in Development</u>	<u>Development Stage</u>	<u>Mechanism/Target</u>	<u>Clinical Indication(s)</u>
Angiomax	Marketed	Direct thrombin inhibitor	U.S. — for use as an anticoagulant in patients undergoing PCI EU — for use as an anticoagulant in patients with ACS or STEMI undergoing primary PCI
Cleviprex	Marketed in the United States; MAA submitted in European Union	Calcium channel blocker	Blood pressure reduction when oral therapy is not feasible or not desirable
Cangrelor	Phase 3	Antiplatelet agent	Prevention of platelet activation and aggregation
Oritavancin	Phase 3	Antibiotic	Treatment of serious gram-positive bacterial infections, including ABSSSI
CU2010	Phase 1	Serine protease inhibitor	Reduction of blood loss during surgery
ApoA-I Milano	Phase 1 /Technology Transfer	Naturally occurring variant of a protein found in HDL	Reversal of atherosclerotic plaque development and reduction of the risk of coronary events in patients with ACS
Ready-to-Use Argatroban	Phase 3; NDA filed	Direct thrombin inhibitor	Anticoagulant for prophylaxis or treatment of thrombosis in patients with or at risk for HIT, and for patients with or at risk for HIT undergoing PCI

*Angiomax.* We market Angiomax, an intravenous direct thrombin inhibitor that is a peptide compound, primarily in the United States and in Europe, where we market Angiomax under the name Angiox® (bivalirudin) to interventional cardiologists and other key decision makers in cardiac catheterization laboratories. Angiomax is approved in the United States and Europe for use in patients undergoing percutaneous coronary intervention, or PCI, including in patients with or at risk of heparin induced thrombocytopenia and

thrombosis syndrome, or HIT/HITTS, a complication of heparin administration that can result in limb amputation, renal failure and death. Angiox is also approved in Europe for use in adult patients with acute coronary syndrome, or ACS. In December 2009, the European Agency for the Evaluation of Medical Products, or EMEA, approved the use of Angiox in the European Union for the treatment of ST-segment elevation myocardial infarction, or STEMI, patients undergoing primary PCI.

The principal U.S. patent covering Angiomax expires on March 23, 2010. We will then have a six-month period of market exclusivity for Angiomax in the United States which will expire on September 23, 2010 due to our study of Angiomax in the pediatric setting. We applied, under the Hatch-Waxman Act, for an extension of the term of this patent. However, the United States Patent Trademark Office, or PTO, rejected our application because in its view the application was not timely filed. We have filed suit against the PTO, the FDA and the U.S. Department of Health and Human Services seeking to set aside the denial of our application to extend the term of the principal patent. We have also sought legislative action to address the matter. In addition, the PTO recently issued two patents to us covering a more consistent and improved Angiomax drug product and the processes by which it is made. In October 2009 and January 2010, we filed suit against pharmaceutical companies which have filed abbreviated new drug applications, or ANDAs, with the FDA for generic versions of Angiomax, alleging infringement of the two recently issued patents. If we are unsuccessful in extending the term of the principal patent and depending on the protection afforded by our two new patents, Angiomax could be subject to generic competition in the United States as early as September 23, 2010. In Europe, the principal patent covering Angiox expires in 2015.

*Cleviprex.* We market Cleviprex, an intravenous small molecule calcium channel blocker, to anesthesiology/surgery, critical care and emergency department practitioners in the United States for the reduction of blood pressure when oral therapy is not feasible or not desirable. Other than in New Zealand, Cleviprex is not approved for sale outside the United States. During the first quarter of 2009, we submitted to member states of the European Union, pursuant to the European Union's decentralized procedure, marketing authorization applications, or MAAs, for Cleviprex for the reduction of blood pressure when rapid and predictable control is required.

On December 16, 2009, we conducted a voluntary recall of 11 lots of Cleviprex due to the presence of visible particulate matter that was deposited at the bottom of some vials and was observed in such vials during a routine annual inspection. We are scheduled to extend our voluntary recall in March 2010 to include four additional manufactured lots of Cleviprex that now also show visible particulate matter that was deposited at the bottom of some vials. As a result, we are not able to supply the market at this time with existing inventory or using the current manufacturing method. We are cooperating with the FDA and our contract manufacturer on these recalls and to remedy the problem at the manufacturing site. If the manufacturing problem is remedied, we anticipate being able to supply the market in the second quarter of 2010. If the problem is not remedied, we may pursue production of drug product using other approaches, which could delay the supply of Cleviprex up to 18 months.

*Cangrelor.* Cangrelor is an intravenous small molecule antiplatelet agent that we are developing to prevent platelet activation and aggregation that leads to thrombosis in the critical care setting of the cardiac catheterization laboratory to address unmet medical needs in patients with ACS or undergoing PCI. In 2009, we discontinued enrollment in our Phase 3 CHAMPION clinical trial program of cangrelor in patients undergoing PCI after the Independent Analysis Review Committee for the program reported to us that the efficacy endpoints of the trial program would not be achieved. However, our analysis of the 48-hour and 30-day CHAMPION data revealed strong evidence of pharmacological effects, clinical effectiveness and suitable safety in patients undergoing PCI. Subject to the completion of ongoing discussions with the FDA, leading experts in ischemic heart disease and AstraZeneca AB, or AstraZeneca, which licensed cangrelor to us, we plan to initiate a new Phase 3 clinical trial of cangrelor in 2010.

*Oritavancin.* Oritavancin is a novel intravenous antibiotic that we are developing for the treatment of serious gram-positive bacterial infections, including acute bacterial skin and skin structure infections, or ABSSSI (which were formerly referred to as complicated skin and skin structure infections, or cSSSI), *Clostridium difficile* infections, or *C. difficile*, which are infections of the gastro-intestinal tract, bacteremia,

which is an infection involving bacteria in the blood, anthrax and other possible indications. We acquired oritavancin in February 2009 in connection with our acquisition of Targanta Therapeutics Corporation, or Targanta. Subject to the completion of ongoing discussions with the FDA, we expect to commence a Phase 3 clinical trial of oritavancin in 2010 for the treatment of ABSSSI. We expect to use a simplified dosing regimen involving a single dose of oritavancin in the Phase 3 trial, based upon data generated from a Phase 2 clinical study of oritavancin conducted by Targanta prior to the acquisition. We do not plan to use the dosing regimens used in the previous Phase 3 clinical trials for oritavancin. We expect to initiate Phase 1 studies of an oral formulation of oritavancin for the treatment of *C. difficile* in 2010.

*CU2010.* CU2010 is an intravenous small molecule serine protease inhibitor that we are developing as an intravenous drug for the reduction of blood loss during surgery. We acquired CU2010 in August 2008 in connection with our acquisition of Curacyte Discovery GmbH, or Curacyte Discovery. In preclinical studies, the compound has demonstrated a favorable pharmacokinetic profile for the surgical setting with a rapid onset and offset of effect, due to its short half life. We commenced a Phase 1 clinical trial of CU2010 in Switzerland in July 2009 and plan to submit an investigational new drug application, or IND, for CU2010 to the FDA in 2010. Subject to FDA's review of the IND, we plan to commence a clinical trial of CU2010 in 2010 in patients undergoing coronary artery bypass graft surgery, or CABG surgery, a procedure in which surgeons bypass a blockage in the patient's artery by grafting a vein to the artery on both sides of the blockage to restore blood flow around the obstruction.

*ApoA-I Milano.* ApoA-I Milano is a naturally occurring variant of a protein found in human high-density lipoprotein, or HDL, that we licensed from Pfizer Inc., or Pfizer, in December 2009. Based upon multiple non-clinical studies and a Phase 1/2 clinical trial of ApoA-I Milano conducted prior to our license of this product candidate, we believe that ApoA-I Milano has the potential to reverse atherosclerotic plaque development and reduce the risk of coronary events in patients with ACS. We expect to complete in 2010 a technology transfer program with Pfizer related to Pfizer's clinical development and manufacturing work so that we can begin to manufacture new material using improved manufacturing methodologies developed by Pfizer since the Phase 1/2 trial, with a view towards commencing non-clinical and clinical studies of ApoA-I Milano in 2011.

*Ready-to-Use Argatroban.* In the third quarter of 2009, we licensed marketing rights in the United States and Canada to an intravenous, ready-to-use formulation of Argatroban developed by Eagle Pharmaceuticals, Inc., or Eagle, a specialty pharmaceutical company with expertise in drug development. Argatroban, currently marketed in a concentrated formulation, is approved as an anticoagulant for prophylaxis or treatment of thrombosis in patients with or at risk for heparin induced thrombocytopenia, or HIT, and for patients with or at risk for HIT undergoing PCI. Eagle submitted an NDA for the ready-to-use formulation of Argatroban to the FDA in 2008. In January 2010, Eagle received a complete response letter from the FDA requiring Eagle to submit a new Chemistry, Manufacturing and Control section of the NDA that is complete, up-to-date and corresponds to the ready-to-use formulation of Argatroban. We and Eagle are currently in discussions with the FDA regarding the NDA and expect Eagle to respond to the FDA in 2010.

We market and sell Angiomax and Cleviprex in the United States with a sales force that, as of February 15, 2010, consisted of 132 representatives and managers experienced in selling to hospital customers. In Europe, we market and sell Angiox with a sales force that, as of February 15, 2010, consisted of 51 representatives and managers experienced in selling to hospital customers. Our revenues to date have been generated primarily from sales of Angiomax in the United States, but we continue to expand our sales and marketing efforts in Europe. We believe that by establishing operations in Europe for Angiox, we will be positioned to commercialize our pipeline of critical care product candidates in Europe, if and when they are approved.

Our core strategy is to acquire, develop and commercialize products that we believe will help hospitals treat patients more efficiently by improving the effectiveness and safety of treatment while reducing cost. We believe that we have the skills and experience to identify market needs and generate meaningful clinical data by investing aggressively in research and development, which enhances our ability to successfully pursue this

strategy. Our research and development investments are designed to provide clinical data that measure whether products:

- are effective, safe and predictable;
- enable shorter periods of treatment;
- are easier to use than current products;
- reduce the length of hospital stay; and
- lower hospital costs.

We believe that products with these attributes positively impact patient care and are attractive to the decision-makers who comprise our current and potential customers, including hospital systems, hospital management, physicians, hospital pharmacists, nurses and other care staff.

## **Angiomax**

### *Overview*

We licensed Angiomax from Biogen Idec, Inc., or Biogen Idec, in 1997 and have exclusive license rights to develop, market and sell Angiomax worldwide. We received our first marketing approval for Angiomax from the FDA in December 2000 and our first marketing approval for the European Union in September 2004. We market Angiomax in the United States for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty, or PTCA, and for use in patients undergoing PCI, including patients with or at risk of HIT/HITTS.

In Europe, we market Angiox for use as an anticoagulant in patients undergoing PCI, for use in adult patients with ACS, including specifically patients with unstable angina or non-ST segment elevation myocardial infarction planned for urgent or early intervention when used with aspirin and clopidogrel, a platelet inhibitor which is marketed under the brand name Plavix® by Bristol-Myers Squibb Co./Sanofi Pharmaceuticals Partnership, and for the treatment of STEMI patients undergoing primary PCI. Angiomax is also approved for sale in Australia, Canada and a number of countries in Central America, South America and the Middle East for PCI indications similar to those approved by the FDA. In July 2007, Canadian health authorities approved the use of Angiomax in Canada for the treatment of patients with HIT/HITTS undergoing cardiac surgery.

We market Angiomax to interventional cardiologists and other key decision makers in cardiac catheterization laboratories. In evaluating our operating performance, we focus on use of Angiomax by existing hospital customers and penetration into new hospitals, both of which are critical elements of our ability to increase market share and revenue. In 2009, our net sales of Angiomax totaled approximately \$401.2 million, including approximately \$382.9 million of net sales in the United States.

The principal U.S. patent covering Angiomax expires on March 23, 2010. We will then have a six-month period of market exclusivity for Angiomax in the United States which will expire on September 23, 2010 due to our study of Angiomax in the pediatric setting. We applied, under the Hatch-Waxman Act, for an extension of the term of the principal patent. However, the PTO rejected our application because in its view the application was not timely. We have filed suit against the PTO, the FDA and the U.S. Department of Health and Human Services seeking to set aside the denial of our application to extend the term of the principal patent covering Angiomax. We have also sought legislative action to address the matter. In addition, the PTO recently issued two patents to us covering a more consistent and improved Angiomax drug product and the processes by which it is made. In October 2009 and January 2010, we filed suit against pharmaceutical companies which have filed ANDAs with the FDA for generic versions of Angiomax, alleging infringement of the two recently issued patents. If we are unsuccessful in extending the term of the principal patent and depending on the protection afforded by our two new patents, Angiomax could be subject to generic competition in the United States as early as September 23, 2010. In Europe, the principal patent covering Angiox expires in 2015.

### *Medical Need*

Arterial thrombosis is a condition involving the formation of blood clots in arteries that is associated with life-threatening conditions, such as ischemic heart disease, peripheral vascular disease and stroke. Anticoagulation therapy is used for the treatment of arterial thrombosis. Anticoagulation therapy attempts to modify actions of the components in the blood system that lead to the formation of blood clots and is usually started immediately after a diagnosis of blood clots, or after risk factors for clotting are identified. Anticoagulation therapy typically involves the use of drugs to inhibit one or more components of the clotting process and reduces the risk of clot formation. There are three main areas of the hospital where anticoagulants are used for acute treatment of arterial thrombosis:

- the cardiac catheterization laboratory, where coronary angioplasties are performed;
- the emergency department, where patients with ACS, including chest pain and heart attacks, are initially treated; and
- the operating room, where valve replacement surgery and CABG surgery are performed.

Coronary angioplasty procedures inherently increase the risk of clots forming in the coronary arteries or in other arteries of the body. Clots form as the body reacts to the manipulation of the artery as a result of, for example, the use of catheters and other devices in connection with the angioplasty procedure. Accordingly, anticoagulation therapy is routinely administered to patients undergoing angioplasty to slow the clotting process and avoid unwanted clotting in the coronary artery and the potential growth of clots or the movement of a clot or portions of a clot downstream in the blood vessels to new sites.

ACS patients are subject to chest pain that results from a range of conditions, from unstable angina to acute myocardial infarction, or AMI. Unstable angina is caused most often by a rupture of plaque on an arterial wall that results in clot formation and ultimately decreases coronary blood flow but does not cause complete blockage of the artery. Unstable angina is often medically managed in the emergency department with anticoagulation therapy. AMI occurs when coronary arteries, which supply blood to the heart, become completely blocked by a clot. AMI patients are routinely treated with anticoagulants and are increasingly undergoing angioplasty as a primary treatment to unblock clogged arteries.

Many of the most severe ACS patients undergo CABG surgery. A high level of anticoagulation is necessary in on-pump cardiac surgery during the period of cardiopulmonary bypass in order to prevent clots from forming in the machine used in such surgery or in the patient's cardiovascular system. Anticoagulation is also necessary in off-pump cardiac surgery to prevent clots from forming in the patient's cardiovascular system as a result of the manipulation of coronary arteries and the heart.

Heparin has historically been used in the United States as an anticoagulant in the treatment of arterial thrombosis. However, heparin can precipitate the immune response HIT/HITTS and its pharmacokinetics are non-linear making it less predictable and making standardized dosing difficult. In some patients, especially higher risk ACS patients, either higher doses of heparin or adjunct therapy, such as glycoprotein IIb/IIIa, or GP IIb/IIIa, inhibitors, are needed, which can result in higher rates of bleeding. These shortcomings are significant because when anticoagulation is insufficient in patients being treated for ischemic heart disease, the consequences can include death, AMI or revascularization. Revascularization occurs when a treated artery is blocked again and requires re-opening. In addition, because anticoagulation therapy reduces clotting, it also may cause excessive bleeding.

### *Clinical Development*

We have invested significantly in the development of clinical data on the mode of action and clinical effects of Angiomax in procedures including coronary angioplasty and stenting. In our investigations, we have compared Angiomax to various competitive products, including heparin and enoxaparin, a low-molecular weight heparin, which until relatively recently were the only injectable anticoagulants for use in coronary angioplasty, GP IIb/IIIa inhibitors, and combinations of drugs including heparin or enoxaparin and GP IIb/IIIa inhibitors. In total, we have tested Angiomax against heparin or enoxaparin or combinations of drugs including

heparin or enoxaparin and GP IIb/IIIa inhibitors in 12 comparative PCI and ACS trials. In these trials, Angiomax use resulted in rates of complications, such as heart attack, which is also known as myocardial infarction, or MI, that were comparable to the comparator drugs in the trials while resulting in fewer bleeding events, including a reduction in the need for blood transfusion, as compared to the comparator drugs in the trials. In addition, in these trials, the therapeutic effects of Angiomax were shown to be more predictable than the therapeutic effects of heparin.

*REPLACE-2.* We conducted the REPLACE-2 clinical trial in 2001 and 2002 to evaluate Angiomax as the foundation anticoagulant for angioplasty within the context of modern therapeutic products and technologies, including coronary stents. We designed the trial, which involved 6,002 patients in 233 clinical sites, to evaluate whether the use of Angiomax with provisional use of GP IIb/IIIa inhibitors provides clinical outcomes relating to rates of ischemic and bleeding events that are the same as, or non-inferior to, low-dose weight-adjusted heparin plus GP IIb/IIIa inhibitors. The primary objective of REPLACE-2 was to demonstrate non-inferiority to heparin plus a GP IIb/IIIa inhibitor for the quadruple composite effectiveness criteria, or endpoint, of death, MI, urgent revascularization and major bleeding. The secondary objectives of REPLACE-2 included non-inferiority to heparin plus a GP IIb/IIIa inhibitor for a triple composite endpoint of death, MI and urgent revascularization. We assessed these outcomes, using formal statistical tests for non-inferiority. Based on 30-day, 6-month and 12-month patient follow-up results, Angiomax met all primary and secondary objectives for the study. In addition, major hemorrhage was reported significantly less frequently in the Angiomax with provisional GP IIb/IIIa inhibitor arm compared to the heparin plus a GP IIb/IIIa inhibitor arm.

*ACUITY.* In 2004 and 2005, we conducted a 13,819 patient Phase 3 trial, called ACUITY, which studied Angiomax's use in patients presenting to the emergency department with ACS. In ACUITY, we tested whether Angiomax use is safe and effective in ACS patients when it is first administered in the emergency department at a lower dose than that which is currently used in PCI patients. If an emergency department ACS patient subsequently underwent PCI, the dose was increased to provide the usual anticoagulation during the procedure. Outcomes were also measured among ACS patients that did not undergo PCI, namely those patients who were medically managed or who underwent CABG surgery. All of these emergency department ACS patients were randomized into one of three arms:

- a control arm, Arm A, providing for the administration of heparin or enoxaparin with GP IIb/IIIa inhibitors;
- a second arm, Arm B, providing for the administration of Angiomax with planned use of GP IIb/IIIa inhibitors; and
- a third arm, Arm C, providing for the administration of Angiomax alone and permitting use of GP IIb/IIIa inhibitors only in selected cases involving ischemic events during PCI.

The 30-day patient results from the ACUITY trial, which were published in the New England Journal of Medicine in November 2006 by the principal investigators, showed that Angiomax met all primary and secondary pre-specified objectives for the ACUITY study. Specifically, in Arm C, the Angiomax monotherapy arm, Angiomax was effective and reduced the risk of major bleeding by 47% compared to the control arm, Arm A. In the Angiomax combination arm, Arm B, the Angiomax and GP IIb/IIIa combination was as effective, with similar reductions in bleeding, as the control arm. In December 2007, the one-year ACUITY results, which confirmed the ACUITY 30-day results, were published in the Journal of the American Medical Association. A subgroup analysis of the ACUITY trial, which was reported in the Journal of the American College of Cardiology in May 2008, revealed that in the trial switching to Angiomax after pre-treatment with heparin resulted in comparable ischemic outcomes and an approximately 50% reduction in major bleeding compared to consistent heparin therapy plus routine GP IIb/IIIa inhibitor for ACS patients undergoing early invasive treatment.

Based on the results of our Phase 3 ACUITY trial, in December 2006 we submitted an application to the EMEA seeking approval of an additional indication for Angiomax for the treatment of patients with ACS and in July 2007 we submitted a supplemental new drug application, or sNDA, to the FDA seeking approval of an additional indication for Angiomax for an additional dosing regimen in the treatment of ACS initiated in the

emergency department. In January 2008, the EMEA approved our application and authorized the use of Angiox in adult patients with ACS, specifically patients with unstable angina or non-ST segment elevation myocardial infarction planned for urgent or early intervention, when used with aspirin and clopidogrel. In May 2008, we received a non-approvable letter from the FDA with respect to the Angiomax sNDA. In its letter, the FDA indicated that the basis of its decision involved the appropriate use and interpretation of the non-inferiority trials we relied upon in support of our sNDA, including the ACUITY trial. We disagree with the FDA on these issues and continue to evaluate how to respond to the FDA's views on the ACUITY trial.

*HORIZONS AMI.* We supported an investigator-initiated trial called HORIZONS AMI that was conducted from 2005 to 2007 to study Angiomax use in patients with STEMI undergoing PCI. HORIZONS AMI, which involved more than 3,600 patients presenting with STEMI undergoing a primary PCI strategy in hospitals in 11 countries was designed to evaluate whether Angiomax with provisional use of GPIIb/IIIa inhibitors was as safe and effective as heparin with planned use of GPIIb/IIIa inhibitors in PCI patients. The two primary endpoints of the trial were major bleeding and net adverse clinical events, a composite of major bleeding and major adverse cardiovascular events, including death, reinfarction, stroke or ischemic target vessel revascularization. The principal secondary endpoint was major adverse cardiovascular events. The results of HORIZONS AMI, which were reported in the New England Journal of Medicine in May 2008, showed that treatment with Angiomax in the trial, as compared with the heparin arm of the trial, resulted in a statistically significant reduction in the incidence of net adverse clinical events by 24%, major bleeding by 40% and cardiac-related mortality by 38%. In addition, treatment with Angiomax demonstrated comparable rates of major adverse cardiac events. In the one-year follow-up data from the HORIZONS AMI trial, Angiomax showed a statistically significant reduction in the incidence of cardiac-related mortality by 43%; all-cause mortality by 31%; major bleeding by 39%; and net adverse clinical events by 16%. In this data, there was no difference in rates of major adverse cardiac events between Angiomax and the comparator drug therapies. We obtained approval in the European Union for the use of Angiox for the treatment of STEMI patients undergoing primary PCI on the basis of the HORIZONS AMI trial results.

#### *Additional Development*

*EUROMAX.* We are currently conducting a Phase 4 clinical trial of Angiomax, which we refer to as the EUROMAX trial, to assess whether the early administration of Angiox in STEMI patients intended for primary PCI presenting either via ambulance or to referral centers where PCI is not performed improves 30-day outcomes when compared to the current standard of care, heparin plus an optional GP IIb/IIIa inhibitor. We expect to enroll approximately 3,680 patients in the EUROMAX trial, which we plan to conduct in ten European countries. Enrollment for EUROMAX began in Germany on March 12, 2010.

*EUROVISION.* In 2009, we initiated a registry in Europe called EUROVISION, which is designed to study utilization patterns of patients receiving Angiox and collect descriptive outcome and safety data of patients. The study is an open label trial and is planned to enroll 2,000 patients at 70 sites in six European countries. The first patient was enrolled in May 2009 and the study is expected to complete enrollment in December 2010.

*HIT/HITTS Patients.* In December 2005, we submitted an application to the FDA for approval to market Angiomax in patients with or at risk of HIT/HITTS undergoing cardiac surgery after completing four studies in our Phase 3 clinical development program in cardiac surgery. In October 2006, we received a non-approvable letter from the FDA in connection with this application. In the letter, the FDA stated that it did not consider the data that we submitted in support of the application adequate to support approval for this indication because the FDA did not consider the evidence used to qualify patients for inclusion in the trials that formed the basis for our application as a persuasive indicator for the risk of HIT/HITTS. We are evaluating potential next steps. In July 2007, Canadian health authorities approved the use of Angiomax in Canada for the treatment of patients with HIT/HITTS undergoing cardiac surgery.

## Cleviprex

### *Overview*

We licensed Cleviprex in March 2003 from AstraZeneca. Under the terms of the agreement, we have exclusive license rights to develop, market and sell Cleviprex worldwide. We received our first marketing approval for Cleviprex from the FDA in August 2008 for the reduction of blood pressure when oral therapy is not feasible or not desirable. In July 2009, Cleviprex was approved for sale in New Zealand for indications similar to those approved by the FDA. During the first quarter of 2009, we submitted to member states of the European Union, pursuant to the European Union's decentralized procedure, MAAs for Cleviprex for the reduction of blood pressure when rapid and predictable control is required. We have also submitted applications for approval to market Cleviprex in Australia, Canada and Switzerland. We are currently evaluating Cleviprex in additional patient populations in numerous Phase 4 and other clinical studies.

We market Cleviprex to anesthesiology/surgery, critical care and emergency department practitioners in the United States. We use the same sales force that sells Angiomax in the United States to sell Cleviprex. In 2009, Cleviprex net sales were approximately \$3.0 million.

On December 16, 2009, we conducted a voluntary recall of 11 lots of Cleviprex due to the presence of visible particulate matter that was deposited at the bottom of some vials and was observed in such vials during a routine annual inspection. We are scheduled to extend our voluntary recall in March 2010 to include four additional manufactured lots of Cleviprex that now also show visible particulate matter that was deposited at the bottom of some vials. As a result, we are not able to supply the market at this time with existing inventory or using the current manufacturing method. We are cooperating with the FDA and our contract manufacturer on these recalls and to remedy the problem at the manufacturing site. If the manufacturing problem is remedied, we anticipate being able to supply the market in the second quarter of 2010. If the problem is not remedied, we may pursue production of drug product using other approaches, which could delay the supply of Cleviprex up to 18 months.

### *Medical Need*

Increases in blood pressure, which are sometimes rapid and acute, often occur in patients treated in a critical care setting. Hospital physicians administer intravenous antihypertensive drugs to control high blood pressure, or acute hypertension, because prolonged severe hypertension is known to cause irreversible damage to the brain, heart, kidneys and blood vessels. Similarly, blood pressure that is too low is also known to cause organ dysfunction and potential damage, particularly ischemia of the heart and brain. As a result, physicians strive to control blood pressure within a range to ensure safe treatment of the patient.

During the twelve-month period ending October 31, 2008, patients made an estimated 3.3 million hospital visits in the United States for conditions requiring treatment with an intravenous antihypertensive. These patients include patients presenting to the emergency department and patients undergoing surgery. Of these patients, approximately:

- 1.7 million medically managed patients were administered intravenous anti-hypertensives;
- 1.1 million surgical intervention patients were administered intravenous anti-hypertensives in connection with surgical procedures, and of these, approximately 475,000 patients were treated with intravenous anti-hypertensives in cardiac and vascular surgery; and
- 556,000 "all other" patients were administered intravenous anti-hypertensives.

In 2007, we surveyed 259 cardiologists, neurologists, surgeons and other critical care specialists to describe the features of an intravenous antihypertensive that they would value, along with the benefits they would expect to achieve. Approximately 90% of these physicians identified rapid onset, efficacy, few side effects and easy titration as important features that guide their selection of an intravenous antihypertensive medication.



Cleviprex belongs to a well-known class of drugs, called intravenous calcium channel blockers, which are used to control acute high blood pressure. Cleviprex acts by selectively relaxing the smooth muscle cells that line small arteries, resulting in widening of the artery and reduction of blood pressure. However, unlike most other calcium channel blockers, Cleviprex is metabolized in the blood and tissue and does not accumulate in the body, which results in an ultra-short half-life. We believe that Cleviprex is well suited for lowering blood pressure in the critical care setting because its rapid onset and offset effect, its selective activity on arteries and its ability to be cleared from the body independent of organ function provide rapid, reliable and predictable blood pressure control with ease of use and a favorable safety profile. In addition, due to its mode of metabolism, we believe that Cleviprex is suitable for a wide range of patients.

### *Clinical Development*

We developed Cleviprex in a clinical trial program comprised of six Phase 3 clinical trials. The results of each of these trials formed the basis of our applications for marketing approval.

*ESCAPE.* We conducted two Phase 3 efficacy clinical trials of Cleviprex, which we refer to as the ESCAPE trials, to evaluate the effectiveness of Cleviprex in approximately 152 patients in controlling blood pressure before and after cardiac surgery compared to a placebo control. The protocol-defined objective for both trials, as measured by rates of treatment success was defined as at least a 15% reduction in blood pressure within 30 minutes without the need to use an alternate drug. Cleviprex met this objective in both trials.

*ECLIPSE.* We conducted three Phase 3 clinical trials, which we refer to as the ECLIPSE trials, to evaluate the safety of Cleviprex in approximately 1,500 patients in comparison to sodium nitroprusside, nicardipine and nitroglycerine, three leading marketed blood pressure-reducing agents, before, during and following cardiac surgery. The protocol-defined safety objectives for all three trials included primary endpoints measured by the incidences of death, stroke, myocardial infarction and renal dysfunction, and secondary objectives measuring blood pressure control. Cleviprex met these objectives in all three trials.

*VELOCITY.* We conducted our sixth Phase 3 clinical trial of Cleviprex, which we refer to as the VELOCITY trial, to evaluate Cleviprex in over 100 patients with acute severe hypertension in the emergency room and critical care unit. The primary efficacy endpoint was the percentage of patients in whom blood pressure was successfully reduced to the target blood pressure range within 30 minutes of initiating therapy. Cleviprex met the primary endpoint of this study, demonstrating a rapid reduction in blood pressure, to the specified blood pressure range, in over 90% of patients within 30 minutes with a very low incidence of overshoot. Subset analyses, which were presented at the annual meeting of the Society of Clinical Care Medicine, or SCCM, in February 2008, further demonstrated Cleviprex's safety and efficacy in high risk patients, such as those with heart and renal failure. According to such subset analyses, in this study, Cleviprex rapidly achieved and maintained blood pressure control in patients with renal dysfunction and patients with acute heart failure.

*Additional Development.* We have been conducting numerous Phase 4 and other clinical studies of Cleviprex in areas such as intracranial hemorrhage, major cardiovascular surgery, neurocritical care and hypertension associated with congestive heart failure, along with health economics analyses. We were also supporting observational studies conducted by hospitals and third-party researchers which include the assessment of acute severe hypertension treatment practices. Some Cleviprex drug product used for clinical trials was manufactured in separate lots from the drug product manufactured for commercial use. These clinical lots have not shown visible particulate matter to date. We will continue to conduct our ACCELERATE, PRONTO, SPRINT and MERCURY Phase 4 trials, described below. Due to the recall of Cleviprex however, the observational studies conducted by hospitals and third-party researchers have been discontinued until such time that we are able to resupply the market with Cleviprex. Our Phase 4 trials are:

- Our ACCELERATE trial, evaluating the efficacy and safety of intravenous infusion of Cleviprex for the treatment of acute hypertension in patients with intracerebral hemorrhage. Interim data from this trial

was presented at the Neurocritical Care Society's 2009 Annual Meeting in November 2009. These data showed that:

- 100% of patients achieved target blood pressure within 30 minutes of Cleviprex initiation;
- median time to target blood pressure was 6.5 minutes;
- 97% of patients did not need additional or alternative intravenous anti-hypertensives during the initial 30-minute period of Cleviprex therapy to reach the target blood pressure; and
- there were no instances of hypotension and no need for supplemental therapy to raise blood pressure in the initial 30-minute period of Cleviprex therapy;
- Our PRONTO trial, evaluating the efficacy and safety of an intravenous infusion of Cleviprex as compared with standard-of-care intravenous antihypertensives for blood pressure lowering in patients with acute heart failure and elevated blood pressure;
- Our SPRINT trial, which has completed its clinical phase, evaluating the pharmacokinetics and pharmacodynamics of a bolus dosing regimen of Cleviprex for the management of blood pressure in cardiac surgery patients; and
- Our MERCURY trial, a retrospective observational registry, studying the use and impact of Cleviprex therapy initiated in the emergency department in the management of patients with acute blood pressure elevations, assessed through the end of the initial hospitalization.

## **Cangrelor**

### *Overview*

We exclusively licensed cangrelor in December 2003 from AstraZeneca. Under the terms of our agreement with AstraZeneca, we have exclusive license rights to develop, market and sell cangrelor worldwide, excluding Japan, China, Korea, Taiwan and Thailand. We are developing cangrelor for use as an intravenous antiplatelet agent to prevent platelet activation and aggregation that leads to thrombosis in the critical care setting of the cardiac catheterization laboratory to address unmet medical needs in patients with ACS or undergoing PCI.

Under our license agreement with AstraZeneca, we were required to file an NDA for cangrelor by December 31, 2009. Because we did not satisfy this requirement, AstraZeneca has the right to terminate our rights under the license to develop, market and sell cangrelor in the United States, subject to conducting discussions with us regarding reasonable solutions to the delay in the filing. We are currently discussing with AstraZeneca this matter and our proposed Phase 3 clinical trials for cangrelor.

### *Medical Need*

In the cardiac catheterization laboratory, the use of antiplatelet agents to block platelet activation and reduce the risk of clot formation is considered important therapy because several studies of oral platelet inhibitors have demonstrated better patient outcomes in coronary angioplasty when these agents are administered before the initiation of the procedure.

There is currently no intravenous drug that primarily inhibits platelet activation. One of the leading oral platelet inhibitors is clopidogrel, which, like cangrelor, acts by blocking the adenosine diphosphate receptor. Clopidogrel is commonly administered at a high dose by giving patients four to eight oral tablets before an angioplasty procedure. This practice is known as pre-loading. Although clopidogrel pre-loading has been shown to improve ischemic outcomes in coronary angioplasty, there are several safety and convenience issues with the use of this agent in critical care practice:

- Clopidogrel requires liver metabolism to form the active agent; therefore, the pre-loading dose may require up to six hours to achieve its full effect.

- There does not appear to be a consistent relationship between increased dosage of clopidogrel and intended effect across different patient groups.
- The inhibition of platelet function is irreversible, meaning the agent remains bound to receptors for the life of the platelet, which is typically ten days. This may impede patient management and treatment flexibility, as well as increase the potential for bleeding, especially if a patient needs cardiac surgery, which is usually delayed for days awaiting the generation and release of new platelets from the bone marrow.
- Oral agents like clopidogrel are difficult to administer in the critical care setting because they need to be swallowed by patients who may have received light anesthesia. This is especially true when there is a need to swallow multiple tablets in a restricted period of time.

Based on input from our hospital customers in the cardiac catheterization laboratory, we believe that the combination of the reduction in ischemic events through platelet inhibition and the critical care limitations of current oral therapy have created a need for an injectable platelet inhibitor that acts quickly and is cleared from the bloodstream rapidly.

In order to minimize bleeding complications, patients undergoing surgery, including CABG surgery, are taken off antiplatelet therapy 5 to 10 days prior to surgery. However, this alone significantly increases the risk that during the period prior to the surgical procedure or during the surgical procedure the patient will develop clots around the preexisting stent. Currently, physicians face the difficult choice of discontinuing antiplatelet therapy prior to surgery and risking a potential ischemic event in the unprotected perioperative period or delaying surgery until the time at which the antiplatelet therapy is no longer required. There are no short-acting platelet inhibitors available that allow maintenance of platelet inhibition before surgery without increasing bleeding complications at the time of surgery. We believe that an ultra short-acting reversible platelet inhibitor, which would maintain platelet inhibition at target levels and allow rapid restoration of platelet function after discontinuation may allow patients to undergo surgical procedures without increasing the risk of bleeding complications while maintaining ischemic protection. We are developing cangrelor to address this market.

### *Clinical Development*

*CHAMPION Program.* In May 2009, we discontinued enrollment in our Phase 3 clinical trial program for cangrelor. This program consisted of two trials, CHAMPION-PCI and CHAMPION PLATFORM, which we designed to evaluate cangrelor's effectiveness and safety in preventing ischemic events in patients who require PCI. In these trials, cangrelor was compared to the use of eight 75 mg clopidogrel tablets (600 mg). The primary composite endpoint of the CHAMPION-PCI trial measured death, MI, or urgent revascularization at 48 hours after the procedure and the CHAMPION-PLATFORM trial measured the composite endpoint of death, MI, or urgent revascularization at 48 hours after the procedure. Approximately 14,000 patients in the aggregate, reflecting approximately 98% of targeted patients in CHAMPION PCI and 84% in CHAMPION PLATFORM, which was approximately, had been enrolled in these trials when we discontinued enrollment in the clinical trial program after the Independent Analysis Review Committee for the program reported to us that the efficacy endpoints of the trial program would not be achieved. However, our analysis of the 48-hour and 30-day CHAMPION data revealed strong evidence of pharmacological effects, clinical effectiveness and suitable safety in patients undergoing PCI. In November 2009, the results of the CHAMPION trials were, in parallel, published in two New England Journal of Medicine papers and presented at the American Heart Association Scientific Sessions 2009. Analysis of the data demonstrated that compared to the use of clopidogrel use of cangrelor in patients undergoing PCI resulted in:

- marked reductions in important secondary clinical endpoints of death, Q-wave MI, ischemia-driven revascularization and stent thrombosis;
- superior platelet inhibition at the time of PCI; and
- no increase in major bleeding.

Subject to the completion of ongoing discussions with the FDA, leading experts in ischemic heart disease and AstraZeneca, we plan to initiate a new Phase 3 clinical trial of cangrelor in 2010, which we will refer to as CHAMPION Phoenix. We currently expect to enroll between 8,000 and 10,000 patients in the CHAMPION Phoenix trial.

*BRIDGE.* In the fourth quarter of 2008, we commenced a clinical trial, which we refer to as the BRIDGE trial, to assess the use of prolonged cangrelor infusion as a platelet inhibiting bridge for patients who need to discontinue clopidogrel before cardiac surgery. The BRIDGE study aims to establish the dosage of cangrelor that achieves greater than or equal to 60% inhibition of platelet aggregation for up to five days. We expect to complete the BRIDGE trial in 2010.

## **Oritavancin**

### *Overview*

We obtained rights to oritavancin as a result of our acquisition of Targanta in February 2009. Oritavancin is a novel intravenous antibiotic that we are developing for the treatment of serious gram-positive bacterial infections. It is synthetically modified from a naturally occurring compound. Oritavancin was originally discovered and developed by Eli Lilly and Company, or Eli Lilly, to combat a broad spectrum of gram-positive pathogens in response to the emergence of resistance to vancomycin, the most commonly prescribed antibiotic for resistant gram-positive infections. We have exclusive rights to develop, market and sell oritavancin worldwide under a license agreement with Eli Lilly.

In February 2008, Targanta submitted an NDA to the FDA seeking to commercialize oritavancin for the treatment of ABSSSI, including infections caused by methicillin-resistant *staphylococcus aureus*, or MRSA. On December 8, 2008, the FDA issued a complete response letter to Targanta indicating that the NDA could not be approved in its present form. In its letter, the FDA stated that the NDA did not contain sufficient evidence to demonstrate the safety and efficacy of oritavancin for treatment of ABSSSI. In particular, the FDA stated that while the Phase 3 trial called ARRI, provided evidence of activity of oritavancin, it did not provide substantial evidence alone or in combination with the second, smaller Phase 3 clinical trial, called ARRD, to support the efficacy and safety of oritavancin. In addition, the FDA stated that in ARRI, oritavancin did not appear to perform well in patients with MRSA and that in ARRD the number of patients with MRSA was insufficient to address the performance of oritavancin in treating these patients. The FDA also referenced several safety findings from the trials in its letter, including the higher rate of study discontinuations for lack of efficacy among oritavancin-treated patients, the greater number of oritavancin-treated patients who died or had a serious adverse event of sepsis, septic shock and related events, and more oritavancin-treated patients who experienced adverse events of osteomyelitis and sepsis. The FDA indicated that it would be necessary to perform an additional adequate and well-controlled study to demonstrate the safety and efficacy of oritavancin in patients with ABSSSI.

Subject to the completion of ongoing discussions with the FDA, we plan to commence a Phase 3 trial of oritavancin in 2010 in approximately 2,200 to 2,300 patients for the treatment of ABSSSI. We plan to use a simplified dosing regimen involving a single dose of oritavancin in the Phase 3 trial based upon data generated from Targanta's SIMPLIFI clinical study described below and not to use the dosing regimens used in the previous Phase 3 trials of oritavancin.

In June 2008, Targanta submitted an MAA to the EMEA seeking approval of oritavancin for the treatment of complicated skin and soft tissue infections, or cSSTI, caused by methicillin susceptible and resistant gram-positive bacteria. We withdrew this MAA in August 2009 after the EMEA expressed issues similar to those raised by the FDA in its complete response letter.

### *Medical Need*

Although there are a number of approved antibiotics for the treatment of gram-positive infections, these antibiotics have important shortcomings, including:

- bacteria are increasingly becoming resistant to one or more of these existing antibiotics;

- some of these antibiotics, referred to as bacteriostatic drugs, solely inhibit the growth of pathogens and rely on the immune system to actually kill the bacteria. Bacteriostatic drugs are less effective in treating patients with compromised immune systems that cannot rid their bodies of the pathogens;
- many of these antibiotics have a narrow spectrum, which is the range of bacteria treated by a drug, and, as a result, are only effective against some serious pathogens but not others;
- many of the antibiotics used to treat serious infections are difficult or inconvenient to administer, as they must be administered twice daily for seven to fourteen days, or longer, with the patients being hospitalized for much or all of this period; and
- many of these antibiotics may cause serious side effects in some patients, sometimes requiring discontinuation of therapy. Due to these side effects, health care providers are required to engage in costly and time-consuming monitoring of blood levels and other parameters.

As a result, there is a significant need for new antibiotics that address the limitations of currently available products. We believe that infectious disease physicians desire new antibiotics with greater efficacy, fewer side effects, fewer administration issues and better hospital economics.

### *Clinical Development*

Oritavancin has been tested in over 1,650 patients and has been the subject of two Phase 3 trials for the treatment of ABSSSI. Eli Lilly and InterMune, Inc., or InterMune, which transferred its rights to oritavancin to Targanta in 2005, conducted these trials. Both of these Phase 3 clinical trials compared treatment with oritavancin to a control arm of vancomycin followed by another antibiotic, cephalexin, using a non-inferiority trial design. In both of the trials, oritavancin met the primary endpoint. In both trials, oritavancin was found to be effective in an average of 5.3 days compared to an average of 10.9 days for the vancomycin / cephalexin control arm. In addition, in these trials, oritavancin was well tolerated and exhibited a favorable safety profile compared to vancomycin. However, in its complete response letter, the FDA identified safety concerns that will need to be addressed in a Phase 3 trial.

In September 2008, Targanta announced positive, preliminary results from its SIMPLIFI Phase 2 clinical study that it commenced in 2007. Targanta designed SIMPLIFI as a three-arm trial in over 300 patients to evaluate the efficacy and safety of a single 1,200 mg dose of oritavancin in Arm A, compared to an infrequent dosing regimen in Arm B of 800 mg of oritavancin on day 1 followed by an optional 400 mg dose of oritavancin on day 5, and to a 200 mg dose of oritavancin given daily for three to seven days in Arm C. The results showed comparable efficacy and safety across all three treatment arms.

In September 2007, Targanta completed a QT study to evaluate the cardiac safety of oritavancin. In this study, Targanta examined the effects of a 200 mg per day dose of oritavancin, which is the dose used in the Phase 3 trials, an 800 mg per day dose of oritavancin, and a single dose of 400 mg of moxifloxacin in a control arm. In this study, none of these doses of oritavancin had an undesirable effect on the cardiac QT interval. Electrocardiography data collected in patients receiving a 1,200 mg per day dose supported the cardiac safety of oritavancin when administered in a single dose of 1,200 mg.

As described above, subject to the completion of ongoing discussions with the FDA, we plan to commence a Phase 3 clinical trial of oritavancin for the treatment of ABSSSI in 2010. We are also exploring the development of oritavancin for other indications, including for the treatment of *C. difficile*, bacteremia, anthrax and other gram positive bacterial infections. We plan to initiate Phase I clinical trial of an oral formulation of oritavancin for *C. difficile* in 2010.

### **CU2010**

We acquired CU2010 in August 2008 as a result of our acquisition of Curacyte Discovery. CU2010 is a small molecule serine protease inhibitor that we are developing for the reduction of blood loss during surgery. Since Bayer Healthcare Pharmaceuticals withdrew Trasylol (aprotinin) from the market in 2008, there has been a significant unmet medical need for a product that reduces blood loss during surgery. The FDA had approved

Trasylol for prophylactic use to reduce perioperative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of coronary artery bypass graft surgery who are at an increased risk for blood loss and blood transfusion. In preclinical studies in animal models, CU2010 has demonstrated a favorable pharmacokinetic profile for the surgical setting with a rapid onset and offset of effect, due to its short half life. We commenced a Phase 1a clinical trial of CU2010 in Switzerland in July 2009 to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics of CU2010 in 32 healthy volunteers. We expect to complete the trial in the second quarter of 2010 and to commence a clinical trial of CU2010 in 2010 in patients undergoing CABG surgery.

### **ApoA-I Milano**

We licensed exclusive worldwide rights to ApoA-I Milano from Pfizer in December 2009. ApoA-I Milano is a naturally occurring variant of a protein found in human HDL that has the potential to reverse atherosclerotic plaque development and reduce the risk of coronary events in patients with ACS. In multiple non-clinical studies, conducted by Pfizer and its predecessors in animal models, ApoA-I Milano rapidly removed excess cholesterol from artery walls, thereby stabilizing and regressing atherosclerotic plaque. In a Phase ½ study conducted by Pfizer from 2001 through 2003 in 36 patients, ApoA-I Milano demonstrated statistically significant reductions in coronary plaque volume by 4.2% in six weeks. These findings were published in the Journal of the American Medical Association. We expect to complete in 2010 a technology transfer program with Pfizer related to Pfizer's clinical development and manufacturing work so that we can begin to manufacture new material using improved manufacturing methodologies developed by Pfizer since the Phase 1/2 trial, with a view towards commencing non-clinical and clinical studies in 2011.

### **Ready-to-Use Formulation Argatroban**

In the third quarter of 2009, we licensed marketing rights in the United States and Canada to a ready-to-use formulation of Argatroban developed by Eagle. Argatroban, currently marketed by GlaxoSmithKline in a concentrated formulation, is approved as an anticoagulant in the United States for prophylaxis or the treatment of thrombosis in patients with or at risk for HIT and for patients with or at risk for HIT undergoing PCI. Eagle submitted an NDA for the ready-to-use formulation of Argatroban to the FDA in 2008. We believe that the ready-to-use formulation of Argatroban is a more efficient delivery system than the currently marketed formulation of Argatroban, which requires mixing by pharmacy and nursing departments. In January 2010, Eagle received a complete response letter from the FDA requiring Eagle to submit a new Chemistry, Manufacturing and Control section of the NDA that is complete, up-to-date and corresponds to the ready-to-use formulation of Argatroban. We and Eagle are currently in discussions with the FDA regarding the NDA and expect Eagle to respond to the FDA in 2010.

### **Sales and Distribution**

We sell Angiomax and Cleviprex in the United States using a hospital sales force that, as of February 15, 2010, consisted of 132 sales representatives and managers. For Angiomax, our sales force targets, as potential hospital customers, hospitals with cardiac catheterization laboratories in the United States that perform approximately 200 or more coronary angioplasties per year. These hospitals conduct a significant percentage of the total number of the coronary angioplasties performed each year in the United States. For Cleviprex, our sales force targets many of the same hospitals, as most institutions with a cardiac catheterization laboratory also perform heart surgeries and have intensive care units as well as emergency rooms.

We distribute Angiomax and Cleviprex in the United States through a sole source distribution model. Under this model, we sell Angiomax and Cleviprex to our sole source distributor, Integrated Commercialization Solutions, Inc., or ICS, which then sells Angiomax and Cleviprex to a limited number of national medical and pharmaceutical wholesalers with distribution centers located throughout the United States and in certain cases, directly to hospitals. Our agreement with ICS, which we initially entered into February 2007, provides that ICS will be our exclusive distributor of Angiomax and Cleviprex in the United States. Under the terms of this fee-for-service agreement, ICS assumes all credit and inventory risks, is subject to our standard return policy, places orders with us for sufficient quantities of Angiomax and Cleviprex to maintain an appropriate

level of inventory based on our customers' historical purchase volumes and has sole responsibility for determining the prices at which it sells Angiomax and Cleviprex, subject to specified limitations in the agreement. The agreement terminates on February 28, 2011, but will automatically renew for additional one-year periods unless either party gives notice at least 120 days prior to the automatic extension. We may also terminate the agreement at any time and for any reason upon prior written notice to ICS and payment of a termination fee of between \$100,000 and \$250,000.

In Europe, we market and sell Angiox with a sales force that, as of February 15, 2010, consisted of 51 representatives and managers experienced in selling to hospital customers, which targets hospitals with cardiac catheterization laboratories that perform approximately 200 or more coronary angioplasties per year. We also market and sell Angiomax outside the United States through distributors, including Sepracor Inc., which distributes Angiomax in Canada, and affiliates of Grupo Ferrer Internacional, which distribute Angiox in Greece, Portugal and Spain and in a number of countries in Central America and South America. We also have agreements with other third parties for other countries outside of the United States and Europe, including Israel and Australia. We are developing a global strategy for Cleviprex in preparation for its potential approval outside of the United States.

In support of sales efforts, we focus our Angiomax marketing in the United States and in Europe on interventional cardiologists and other key clinical decision-makers in cardiac catheterization laboratories and focus our Cleviprex marketing on anesthesiology/surgery, critical care and emergency department practitioners in the United States. We believe our ability to deliver relevant, advanced and reliable service and information to our concentrated customer base provides us with significant market presence in the United States, and will provide us with such presence outside the United States, even in highly competitive sub-segments of the hospital market such as cardiology.

## **Manufacturing**

We do not have a manufacturing infrastructure and do not intend to develop one. We are party to agreements with contract manufacturers to supply bulk drug substance for our products and with other third parties to formulate, package and distribute our products. Our product manufacturing operation is comprised of professionals with expertise in pharmaceutical manufacturing development and logistics and supply chain management. These professionals oversee the manufacturing and distribution of our products by third-party companies.

### *Angiomax*

In December 1999, we entered into a commercial development and supply agreement with Lonza Braine, S.A., which was formerly known as UCB Bioproducts S.A., for the development and supply of Angiomax bulk drug substance. Together with Lonza Braine, we developed a second generation chemical synthesis process to improve the economics of manufacturing Angiomax bulk drug substance. This process, which was approved by the FDA in May 2003 and is used in the manufacture of Angiomax bulk drug substance today, is known as the Chemilog process. We have agreed that, during the term of the agreement, we will purchase a substantial portion of our Angiomax bulk drug substance manufactured using the Chemilog process from Lonza Braine at agreed upon prices. Following the expiration of the agreement or if we terminate the agreement prior to its expiration, Lonza Braine has agreed to transfer the development technology to us. If we engage a third party to manufacture Angiomax for us using the Chemilog process prior to bivalirudin becoming a generic drug in the United States, we will be obligated to pay Lonza Braine a royalty based on the amount paid by us to the third-party manufacturer. Our agreement with Lonza Braine expires in September 2013, subject to automatic renewals of consecutive three-year periods unless either party provides notice of non-renewal within one year prior to the expiration of the initial term or any renewal term. We may only terminate the agreement prior to its expiration in the event of a material breach by Lonza Braine, if such breach is not cured within 30 days.

In October 1997, we entered into a master agreement with Ben Venue Laboratories, Inc., or Ben Venue, for the manufacture of Angiomax drug product. Ben Venue conducts the fill-finish of Angiomax drug product

in the United States for us through purchase order arrangements agreed upon by the parties and governed by the master agreement. In Europe, Almac Pharma Services is responsible for the importation and release of Angiox.

#### *Cleviprex*

In October 2002, we entered into a master research and manufacturing agreement with Johnson Matthey Pharma Services, or Johnson Matthey, for the manufacture of Cleviprex bulk drug substance for us for our clinical trials of Cleviprex and for our commercial requirements. Johnson Matthey manufactures the bulk drug substance under project work orders agreed upon by the parties and governed by the master research and manufacturing agreement.

In December 2003, we entered into a contract manufacturing agreement with Fresenius Kabi Clayton, L.P., which was subsequently assigned to Hospira, Inc., or Hospira. Pursuant to the agreement, Hospira is the exclusive supplier for all finished drug product of Cleviprex using its proprietary formulation technology. The agreement expires August 2018, subject to automatic three-year renewal periods unless either party gives notice at least three-years written notice which may be given any time after December 2015. Either party may terminate the agreement for material breach by the other party, if the material breach is not cured within 60 days after written notice. Upon expiration or termination of the agreement, Hospira is required to grant us a license to Hospira's proprietary technology for the manufacture of Cleviprex.

On December 16, 2009, we conducted a voluntary recall of 11 lots of Cleviprex due to the presence of visible particulate matter that was deposited at the bottom of some vials and was observed in such vials during a routine annual inspection. We are scheduled to extend our voluntary recall in March 2010 to include four additional manufactured lots of Cleviprex that now also show visible particulate matter that was deposited at the bottom of some vials. As a result, we are not able to supply the market at this time with existing inventory or using the current manufacturing method. We are cooperating with the FDA and our contract manufacturer on these recalls and to remedy the problem at the manufacturing site. If the manufacturing problem is remedied, we anticipate being able to supply the market in the second quarter of 2010. If the problem is not remedied, we may pursue production of drug product using other approaches, which could delay the supply of Cleviprex up to 18 months.

#### *Cangrelor*

Johnson Matthey manufactures cangrelor bulk drug substance for us for our clinical trial needs. Johnson Matthey manufactures the bulk drug substance under project work orders agreed upon by the parties and governed by our master research and manufacturing agreement with Johnson Matthey.

In October 2004, we entered into a drug product development and clinical supply agreement with Baxter Pharmaceutical Solutions LLC, or Baxter, a division of Baxter Healthcare Corporation, for the manufacture of a portion of cangrelor finished drug product for our cangrelor clinical trials and to carry out release testing. The agreement expires when the clinical trials, as described in the development plan under the agreement, are completed. Either party may terminate the agreement for breach by the other party, if the breach is not cured after receipt of written notice of the breach within 10 days for monetary defaults and 30 days for non-monetary defaults. Ben Venue supplies the remainder of the cangrelor finished drug product under purchase order arrangements agreed upon by the parties and governed by our master agreement with them. We have not entered into an agreement for commercial supply of cangrelor finished drug product, although we believe our contract manufacturers have the capability to manufacture and package cangrelor on a commercial scale appropriate for launch of the drug when and if cangrelor is approved for sale.

#### *Oritavancin*

Prior to our acquisition of oritavancin, in December 2001, Targanta entered into a development and supply agreement with Abbott Laboratories, or Abbott, for the supply of oritavancin bulk drug substance for clinical use in clinical trials. Under the Abbott agreement, which we acquired with our acquisition of Targanta, we are required to purchase oritavancin bulk drug substance exclusively from Abbott, unless Abbott fails to



deliver sufficient oritavancin bulk drug substance to meet our needs. In such event, we may use another manufacturer to supply oritavancin bulk drug substance for as long as Abbott is unable to supply sufficient oritavancin bulk drug substance. We are also required to purchase a minimum amount of oritavancin bulk drug substance from Abbott. The agreement expires on December 31, 2014, subject to automatic two-year renewal periods unless either party gives at least 24-months written notice of termination during the initial term or 12-months notice during any renewal term. Either party may terminate the agreement upon two-years notice if the party determines that the launch of the product is not technically, clinically or commercially feasible or economically justifiable. Abbott has the right to terminate the agreement at any time upon 30-months notice. Either party may terminate the agreement for breach by the other party, if the breach is not cured after receipt of written notice within 60 days or for breaches of a type that cannot be remedied within 60 days, then a remedy promptly commenced and diligently pursued until complete remediation. Upon termination, Abbott is required to assist us with a technology transfer to us or our designee. We expect to continue to use Abbott as the sole provider of oritavancin bulk drug substance for clinical use.

We obtain oritavancin drug product from Ben Venue under a manufacturing and services agreement Targanta entered into in August 2008. Under the agreement, we have minimum purchase obligations commencing the first full year after the commercial launch of the product. The agreement expires on August 22, 2013. Either party may terminate the agreement for any reason with 24-months written notice or for material breach by the other party, if the material breach is not cured within three months after written notice of the breach. We can terminate the agreement with 90 days written notice in the event oritavancin is withdrawn from the market. Upon termination of the agreement, the parties have agreed to conduct a manufacturing services and technology transfer to a third party. We are currently in discussions with a second contract fill/finish provider.

#### *CU2010*

We currently obtain our supply of CU2010 bulk drug substance and drug product for our early stage clinical trials from a third-party manufacturer in Germany on a purchase order basis.

#### *ApoA-I Milano*

In connection with the license of ApoA-I Milano from Pfizer we acquired sufficient protein to carry out preclinical and early phase clinical studies. We expect to complete in 2010 a technology transfer program with Pfizer related to Pfizer's clinical development and manufacturing work and upon completion of the technology transfer we plan to evaluate third-party manufacturers for the manufacture of the formulated drug product as well as for future protein manufacture. While Pfizer has made progress with improvements to the original manufacturing process for ApoA-I Milano, primarily to reduce the cost to manufacture the drug product to make it commercially viable, we believe additional work will be needed to scale up the manufacturing process in order to have drug product available for use in clinical trials.

#### *Ready-to-Use Argatroban*

In connection with our license of marketing rights to Eagle's formulation of Argatroban, Eagle has agreed to supply us with the ready-to-use product under a supply agreement we entered into with Eagle in September 2009. The supply agreement expires at the earlier of the termination of our license agreement with Eagle or September 24, 2019. Either party may terminate the agreement for material breach by the other party, if the material breach is not cured after receipt of written notice within 30 days or up to 60 days if the breaching party gives notice that it is in good faith attempting to cure the breach.

### **Business Development Strategy**

We intend to continue building our critical care portfolio of hospital products by selectively licensing or acquiring and then developing clinical compound candidates or products approved for marketing. We believe that we have proven capabilities in developing and commercializing in-licensed or acquired critical care drug candidates. We believe that products may be acquired from pharmaceutical companies which are in the process

of refining their own product portfolios and from companies seeking specialist development or commercial collaborations.

In evaluating product acquisition candidates, we plan to continue to seek products that have the potential to provide appropriate evidence of safety and efficacy, together with the potential to reduce a patient's hospital stay. Our acquisition strategy is to acquire global rights for development compounds wherever possible. We may acquire approved products that can be marketed in hospitals by our commercial organization.

*2009 Business Development Activity:*

In 2009, we made three strategic acquisitions that we believe fit our core strategy:

- In February 2009, with our acquisition of Targanta, we acquired oritavancin, a late stage development product candidate which we believe has the potential to provide significant clinical advantages, including superior dosing options, over current intravenous antibiotics that treat serious infections in the hospital setting. We expect that, if approved, oritavancin will initially be used in critical care settings within the hospital including the ICU, surgical suite and the emergency department, where our sales representatives promote our current products.
- In September 2009, we licensed marketing rights in the United States and Canada to a ready-to-use formulation of Argatroban, which, if approved, we expect will be a strategic complement to Angiomax.
- In December 2009, we licensed ApoA-I Milano from Pfizer, which we believe has the potential to provide rapid coronary artery disease modification in at-risk patients. We believe ApoA-I Milano is a strategic fit because, in our development of ApoA-I Milano, we can leverage both our pre-existing relationships in the cardiac catheterization laboratories and with interventional cardiologists and our knowledge of clinical development and economics in the cardiology area.

*Targanta.* In February 2009, we acquired Targanta, a biopharmaceutical company focused on developing and commercializing innovative antibiotics to treat serious infections in the hospital and other institutional settings. Targanta's product pipeline included an intravenous version of oritavancin and a program to develop an oral version of oritavancin for the possible treatment of *C. difficile*.

Under the terms of our agreement with Targanta, we paid Targanta shareholders approximately \$42.0 million in the aggregate at closing, and agreed to pay contingent cash payments of up to an additional \$90.4 million in the aggregate as described below:

- Upon approval from the EMEA for an MAA for oritavancin for the treatment of ABSSSI on or before December 31, 2013, approximately \$15.8 million in the aggregate if such approval is granted between January 1, 2010 and June 30, 2010, and approximately \$10.5 million in the aggregate if such approval is granted between July 1, 2010 and December 31, 2013.
- Upon final approval from the FDA for an NDA for oritavancin for the treatment of ABSSSI (1) within 40 months after the date the first patient is enrolled in a Phase 3 clinical trial of ABSSSI that is initiated by us and (2) on or before December 31, 2013, approximately \$10.5 million in the aggregate.
- Upon FDA approval for an NDA for the use of oritavancin for the treatment of ABSSSI administered by a single dose intravenous infusion (1) within 40 months after the date the first patient is enrolled in a Phase 3 clinical trial of ABSSSI that is initiated by us and (2) on or before December 31, 2013, approximately \$14.7 million in the aggregate. This payment may become payable simultaneously with the payment described in the previous bullet above.
- If aggregate net sales of oritavancin in four consecutive calendar quarters ending on or before December 31, 2021 reach or exceed \$400 million, approximately \$49.4 million in the aggregate.

*Ready-to-Use Argatroban.* In September 2009, we licensed marketing rights in the United States and Canada to a ready-to-use formulation of Argatroban developed by Eagle, for which Eagle has submitted an NDA to the FDA. In January 2010, Eagle received a complete response letter from the FDA requiring Eagle to submit a new Chemistry, Manufacturing and Control section of the NDA that is complete, up-to-date and

corresponds to the ready-to-use formulation of Argatroban. We and Eagle are currently in discussions with the FDA regarding the NDA and expect Eagle to respond to the FDA in 2010. Under the license agreement with Eagle, we paid Eagle a \$5.0 million technology license fee. We also agreed to pay additional approval and commercialization milestones up to a total of \$15.0 million and royalties on net sales of the ready-to-use formulation. Eagle has agreed to supply us with the ready-to-use formulation under a supply agreement we entered into with it in September 2009.

*ApoA-I Milano.* In December 2009, we licensed exclusive worldwide rights to ApoA-I Milano from Pfizer. Under the terms of the agreement, we paid Pfizer an up-front payment of \$10.0 million and agreed to make additional payments upon the achievement of clinical, regulatory and sales milestones up to a total of \$410 million. We also agreed to pay Pfizer single-digit royalty payments on worldwide net sales of ApoA-I Milano. We also paid \$7.5 million to third parties in connection with the license and agreed to make additional payments to them of up to \$12.0 million in the aggregate upon the achievement of specified development milestones and continuing payments based on sales of ApoA-I Milano.

## **Competition**

The development and commercialization of new drugs is highly competitive. We face competition from pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Many of our competitors are substantially larger than we are and have substantially greater capital resources, research and development capabilities and experience, and financial, technical, manufacturing, marketing and human resources than we have. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors.

Our business strategy is based on us selectively licensing or acquiring and then developing clinical compound candidates or products approved for marketing. Our success will be based in part on our ability to build and actively manage a portfolio of drugs that addresses unmet medical needs and creates value in patient therapy. However, the acquisition and licensing of pharmaceutical products is a competitive area, and a number of more established companies, which have acknowledged strategies to license and acquire products, may have competitive advantages, as may emerging companies taking similar or different approaches to product acquisition. Established companies pursuing this strategy may have a competitive advantage over us due to their size, cash flows and institutional experience.

In addition, our competitors may develop, market or license products or other novel technologies that are more effective, safer or less costly than any that have been or are being developed by us, or may obtain marketing approval for their products from the FDA or equivalent foreign regulatory bodies more rapidly than we may obtain approval for ours. We compete, in the case of Angiomax and Cleviprex, and expect to compete, in the cases of our products in development, on the basis of product efficacy, safety, ease of administration and economic value compared to drugs used in current practice or currently being developed.

### *Angiomax*

Due to the incidence and severity of cardiovascular diseases, the market for anticoagulant therapies is large and competition is intense. There are a number of anticoagulant therapies currently on the market, awaiting regulatory approval or in development for the indications for which Angiomax is approved.

Angiomax competes primarily with heparin and enoxaparin, GP IIb/IIIa inhibitors, and combinations of drugs including heparin or enoxaparin and GP IIb/IIIa inhibitors. Heparin is widely used in patients with ischemic heart disease. Heparin is manufactured and distributed by a number of companies as a generic product and is sold at a price that is significantly less than the price for Angiomax. GP IIb/IIIa inhibitors with which Angiomax competes include ReoPro from Eli Lilly and Johnson & Johnson/Centocor, Inc., Integrilin from Schering-Plough Corporation, and Aggrastat from Iroko Pharmaceuticals, LLC and MediCure Inc. GP IIb/IIIa inhibitors are widely used and some physicians believe they offer superior efficacy in high risk patients.

Although in some cases GP IIb/IIIa inhibitors may be complementary to Angiomax, Angiomax may compete with GP IIb/IIIa inhibitors for the use of hospital financial resources. For example, many U.S. hospitals receive a fixed reimbursement amount per procedure for the angioplasties and other treatment therapies they perform. As this amount is not based on the actual expenses the hospital incurs, hospitals may choose to use either Angiomax or a GP IIb/IIIa inhibitor but not necessarily several of the drugs together.

If we are unsuccessful in extending the term of the principal patent and depending on the protection afforded by our two new patents, Angiomax could be subject to generic competition in the United States as early as September 23, 2010.

#### *Cleviprex*

Cleviprex competes with a variety of antihypertensive agents in the critical care setting, many of which are generic and inexpensive. The FDA has approved nine intravenous drugs for the treatment of hypertension in the critical care setting. Physician selection of these agents depends upon patient diagnosis, acuity, relevant surgeries or procedures that may be planned in the near future, comorbidities and end organ damage. Cleviprex therefore, competes with all of these agents.

#### *Cangrelor*

We expect that cangrelor, if approved, will compete with oral platelet inhibitors that are well known and widely used in critical care settings, such as Plavix from Bristol Meyers Squibb/Sanofi Pharmaceuticals Partnership, and prasugrel, an anti-platelet agent from Eli Lilly and Sankyo Co., Ltd. We believe that the combination of the reduction in ischemic events through platelet inhibition and the critical care limitations of current oral therapy have created a need for an injectable platelet inhibitor that acts quickly and is cleared from the bloodstream rapidly.

#### *Oritavancin*

We expect that oritavancin, if approved, will compete with a number of drugs that target serious gram-positive infections acquired or treated in hospitals such as vancomycin, a generic drug that is manufactured by a variety of companies, daptomycin from Cubist Pharmaceuticals, Inc., linezolid from Pfizer Inc., quinupristin/dalfopristin from Sanofi-Aventis and Monarch Pharmaceuticals Inc., telavancin, from Theravance, Inc. and Astellas Pharma Inc., teicoplanin from Sanofi-Aventis, and tigecycline from Pfizer. Each of these drugs is already established in the market, which will make market penetration for oritavancin more difficult. We believe that oritavancin, if approved as a single dose formulation, would provide advantages over other drug therapies by providing a full regimen in a single dose, which would eliminate the need for daily infusions and reduce or eliminate patient hospitalizations.

#### *Ready-to-Use Argatroban*

We expect that the ready-to-use formulation of Argatroban that we recently licensed, if approved, would compete with the currently marketed version of Argatroban promoted by GlaxoSmithKline in addition to other potential direct generic copies or other innovative forms of the product. The GlaxoSmithKline version of Argatroban is indicated as an anticoagulant for prophylaxis or treatment of thrombosis in patients with heparin-induced thrombocytopenia. Argatroban is also indicated as an anticoagulant in patients with or at risk for heparin-induced thrombocytopenia undergoing PCI. We believe that the ready-to-use formulation of Argatroban is a more efficient delivery system than the currently marketed formulation of Argatroban, which requires mixing by pharmacy and nursing departments.

### **Patents, Proprietary Rights and Licenses**

Our success will depend in part on our ability to protect the products we acquire or license by obtaining and maintaining patent protection both in the United States and in other countries. We rely upon trade secrets, know-how, continuing technological innovations, contractual restrictions and licensing opportunities to develop

and maintain our competitive position. We plan to prosecute and defend patents or patent applications we file, acquire or license.

*Angiomax.* We have exclusively licensed from Biogen Idec and Health Research Inc., or HRI, patents and patent applications covering Angiomax and Angiomax analogs and other novel anticoagulants as compositions of matter, and processes for using Angiomax and Angiomax analogs and other novel anticoagulants. Among them, the principal patent, U.S. Patent No. 5,196,404, is set to expire on March 23, 2010 and the principal patent that covers Angiox in Europe expires in 2015. In addition, we own two new patents, U.S. Patent No. 7,528,727, or the '727 patent, and U.S. Patent No. 7,598,343, or the '343 patent, covering a more consistent and improved Angiomax drug product and the processes by which it is made and are set to expire in July 2028. We have also filed and are currently prosecuting a number of patent applications relating to Angiomax.

We are seeking patent term extension in the United States for the principal patent for Angiomax. The PTO rejected our application under the Hatch-Waxman Act for an extension of the term of the patent beyond March 23, 2010 because in its view the application was not timely filed. In October 2002, we filed a request with the PTO for reconsideration of the denial of the application. On April 26, 2007, we received a decision from the PTO denying the application for patent term extension. On December 4, 2009, we filed a second request with the PTO for reconsideration of the denial of the application. On January 8, 2010, we received a decision from the PTO again denying the application for patent term extension. On January 27, 2010, we filed a complaint in the U.S. District Court for the Eastern District of Virginia against the PTO, the FDA and the U.S. Department of Health and Human Services seeking to set aside the denial of our application under the Hatch-Waxman Act to extend the term of the principal patent covering Angiomax.

On June 23, 2008, the United States House of Representatives passed a bill that, if enacted, would have provided the PTO with discretion to consider patent extension applications filed late unintentionally under the Hatch-Waxman Act. The United States Senate, however, adjourned without considering that bill. We continue to advocate for legislation in the current Congress. Congress may consider enacting legislation similar to that passed by the House in June 2008 although there can be no certainty that it will do so.

We have entered into an agreement with Biogen Idec that suspends the statute of limitations relating to any claims, including claims for damages and/or license termination, that Biogen Idec may bring relating to the PTO's rejection of our application under the Hatch-Waxman Act for an extension of the term of the principal Angiomax patent on the grounds that it was filed late. We have also entered into agreements with the law firms involved in the filing that suspend the statute of limitations on our claims against them for the filing. In the third quarter of 2009, we initiated discussions with the two law firms involved in the filing of the application under the Hatch-Waxman Act and are currently in related discussions with Biogen Idec and HRI with respect to the possible resolution of the potential claims among the parties.

In 2009, we were granted two U.S. patents relating to Angiomax. The first, the '727 patent, was issued on September 1, 2009 and expires in July 2028. The '727 patent contains claims which relate to a more consistent and improved Angiomax drug product. The second, the '343 patent, was issued on October 6, 2009 and expires on in July 2028. The '343 patent contains claims which also relate to a more consistent and improved Angiomax drug product made by processes described in the '343 patent. We listed both patents in the FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," which is commonly known as the Orange Book, for Angiomax. In October 2009 and January 2010, in response to Paragraph IV Certification Notice letters we received with respect to ANDAs filed with the FDA seeking approval to market generic versions of Angiomax, we filed lawsuits against the ANDA filers alleging patent infringement of the '727 patent and '343 patent in the U.S. District Court for the District of Delaware, as described in Item 3 of this annual report.

*Cleviprex.* We have exclusively licensed from AstraZeneca rights to patents and patent applications covering Cleviprex as a composition of matter and covering formulations and uses of Cleviprex. Under the license, AstraZeneca is responsible for prosecuting and maintaining the patents and patent applications relating to Cleviprex. We are required to reimburse AstraZeneca for expenses it incurs in connection with the prosecution and maintenance of the patents and patent applications. The principal U.S. patent for Cleviprex is

set to expire in January 2016. An application for patent term extension for the principal U.S. patent is currently pending. In addition, we have filed and are currently prosecuting a number of patent applications relating to Cleviprex covering compositions of matter and uses.

*Cangrelor.* We have exclusively licensed from AstraZeneca rights to patent and patent applications covering cangrelor as a composition of matter and covering formulations and uses of cangrelor. Under the license, AstraZeneca is responsible for prosecuting and maintaining the patents and patent applications relating to cangrelor. We are required to reimburse AstraZeneca for expenses it incurs in connection with the prosecution and maintenance of the cangrelor patents and patent applications. The principal U.S. patent for cangrelor is set to expire in February 2014 if no patent term extension is obtained. In addition, we have also filed and are currently prosecuting a number of patent applications.

*Oritavancin.* As a result of our acquisition of Targanta, we obtained an exclusive license from Eli Lilly to patents and patent applications covering oritavancin, its uses, formulations and analogs. Under this license, we are responsible for prosecuting and maintaining these patents and patent applications. The principal U.S. patent for oritavancin is set to expire in November 2015 if no patent term extension is obtained. We have also filed and are prosecuting a number of patent applications relating to oritavancin and its uses.

*CU2010.* In connection with our acquisition of Curacyte Discovery, we acquired a portfolio of patents and patent applications covering CU2010, its analogs or other similar protease inhibitors. We plan to prosecute and defend these patents and patent applications.

*ApoA-I Milano.* In connection with our acquisition of ApoA-I Milano, we obtained an exclusive license from Pfizer to patents and patent applications covering ApoA-I Milano as compositions of matter, and processes for using ApoA-I Milano and making ApoA-I Milano. We plan to prosecute and defend these patents and patent applications.

*Ready-to-Use Argatroban.* We have exclusively licensed from Eagle rights to a patent application covering certain formulations of Argatroban. Our exclusive license is limited to the United States and Canada. Under this license, Eagle is responsible for prosecuting and maintaining this patent application.

The patent positions of pharmaceutical and biotechnology firms like us can be uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, we do not know whether any of the patent applications we acquire, license or file will result in the issuance of patents or, if any patents are issued, whether they will provide significant proprietary protection or will be challenged, circumvented or invalidated. Because unissued U.S. patent applications filed prior to November 29, 2000 and patent applications filed within the last 18 months are maintained in secrecy until patents issue, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the PTO to determine priority of invention, or in opposition proceedings in a foreign patent office, either of which could result in substantial cost to us, even if the eventual outcome is favorable to us. Even issued patents may not be held valid by a court of competent jurisdiction. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using such technology.

The development of critical care hospital products is intensely competitive. A number of pharmaceutical companies, biotechnology companies, universities and research institutions have filed patent applications or received patents in this field. Some of these patent applications could be competitive with applications we have acquired or licensed, or could conflict in certain respects with claims made under our applications. Such conflict could result in a significant reduction of the coverage of the patents we have acquired or licensed, if issued, which would have a material adverse effect on our business, financial condition and results of operations. In addition, if patents are issued to other companies that contain competitive or conflicting claims with claims of our patents and such claims are ultimately determined to be valid, we may not be able to obtain licenses to these patents at a reasonable cost, or develop or obtain alternative technology.

We also rely on trade secret protection for our confidential and proprietary information. However, others may independently develop substantially equivalent proprietary information and techniques. Others may also otherwise gain access to our trade secrets or disclose such technology. We may not be able to meaningfully protect our trade secrets.

It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements generally provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees and consultants, the agreements provide that all inventions conceived by the individual shall be our exclusive property. These agreements may not provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

We have a number of trademarks that we consider important to our business. The Medicines Company® name and logo, Angiomax®, Angiox® and Cleviprex® names and logos are either our registered trademarks or our trademarks in the United States and other countries. We have also registered some of these marks in a number of foreign countries. Although we have a foreign trademark registration program for selected marks, we may not be able to register or use such marks in each foreign country in which we seek registration. We believe that our products are identified by our trademarks and, thus, our trademarks are of significant value. Each registered trademark has a duration of ten to 15 years, depending on the date it was registered and the country in which it is registered, and is subject to an infinite number of renewals for a like period upon continued use and appropriate application. We intend to continue the use of our trademarks and to renew our registered trademarks based upon each trademark's continued value to us.

#### *License Agreements*

A summary of our licenses to our products and products in development is set forth below.

*Angiomax.* In March 1997, we entered into an agreement with Biogen, Inc., a predecessor of Biogen Idec, for the license of the anticoagulant pharmaceutical bivalirudin, which we have developed and market as Angiomax. Under the terms of the agreement, we acquired exclusive worldwide rights to the technology, patents, trademarks, inventories and know-how related to Angiomax. In exchange for the license, we paid \$2.0 million on the closing date and are obligated to pay up to an additional \$8.0 million upon the first commercial sales of Angiomax for the treatment of AMI in the United States and Europe. In addition, we are obligated to pay royalties on sales of Angiomax and on any sublicense royalties on a country-by-country basis earned until the later of the date 12 years after the date of the first commercial sales of the product in a country and the date on which the product or its manufacture, use or sale is no longer covered by a valid claim of the licensed patent rights in such country. The royalty rate due to Biogen Idec on sales increases as annual sales of Angiomax increase. Under the agreement, we are obligated to use commercially reasonable efforts to develop and commercialize Angiomax in the U.S. and specified European markets, including for PTCA and AMI indications. The license and rights under the agreement remain in force until our obligation to pay royalties ceases. Either party may terminate the agreement for material breach by the other party, if the material breach is not cured within 90 days after written notice. In addition, we may terminate the agreement for any reason upon 90 days prior written notice. During 2009, we incurred approximately \$77.4 million in royalties related to Angiomax under our agreement with Biogen Idec.

In March 1997, in connection with entering into the Biogen Idec license, Biogen Idec assigned to us a license agreement with HRI under which Biogen Idec had licensed HRI's right to a specified patent application held jointly with Biogen Idec which resulted in the principal U.S. patent covering Angiomax. Under the terms of the agreement, we have exclusive worldwide rights to HRI's rights to the licensed patent application and patents arising from the licensed patent application, other than rights for noncommercial research and educational purposes, which HRI retained. We are obligated to pay royalties on sales of Angiomax and on any sublicense income we earn. The royalty rate due to HRI on sales increases as annual sales of Angiomax increase. Under the agreement, we are obligated to use commercially reasonable efforts to research and

develop, obtain regulatory approval and commercialize Angiomax. The license and rights under the agreement remain in force until the expiration of the last remaining patent granted under the licensed patent application. HRI may terminate the agreement for a material breach by us, if the material breach is not cured within 90 days after written notice or, in the event of bankruptcy, liquidation or insolvency, immediately on written notice. In addition, we may terminate the agreement for any reason upon 90 days' prior written notice upon payment of a termination fee equal to the minimum royalty fee payable under the license agreement.

*Cleviprex.* In March 2003, we licensed from AstraZeneca exclusive worldwide rights to Cleviprex for all countries other than Japan. In May 2006, we amended our license agreement with AstraZeneca to provide us with exclusive license rights in Japan in exchange for an upfront payment. Under the terms of the agreement, we have the rights to the patents, trademarks, inventories and know-how related to Cleviprex. We paid AstraZeneca \$1.0 million in 2003 upon entering into the license and agreed to pay up to an additional \$5.0 million upon reaching agreed upon regulatory milestones, of which we paid \$1.5 million in September 2007 as a result of the FDA's acceptance to file of our NDA for Cleviprex for the treatment of acute hypertension and a payment of \$1.5 million as a result of Cleviprex's approval for sale by the FDA. We are obligated to pay royalties on a country-by-country basis on annual sales of Cleviprex, and on any sublicense income earned, until the later of the duration of the licensed patent rights which are necessary to manufacture, use or sell Cleviprex in a country and the date ten years from our first commercial sale of Cleviprex in such country. Under the agreement, we are obligated to use commercially reasonable efforts to develop, market and sell Cleviprex.

The licenses and rights under the agreement remain in force on a country-by-country basis until we cease selling Cleviprex in such country or the agreement is otherwise terminated. We may terminate the agreement upon 30 days' written notice, unless AstraZeneca, within 20 days of having received our notice, requests that we enter into good faith discussions to redress our concerns. If we cannot reach a mutually agreeable solution with AstraZeneca within three months of the commencement of such discussions, we may then terminate the agreement upon 90 days' written notice. Either party may terminate the agreement for material breach upon 60 days prior written notice if the breach is not cured within such 60 days. During 2009, we incurred approximately \$0.4 million in royalties related to Cleviprex under our agreement with AstraZeneca.

*Cangrelor.* In December 2003, we licensed from AstraZeneca exclusive rights to cangrelor for all countries other than Japan, China, Korea, Taiwan and Thailand. Under the terms of the agreement, we have the rights to the patents, trademarks, inventories and know-how related to cangrelor. We paid an upfront payment of \$1.5 million upon entering into the license and agreed to make additional milestone payments of up to \$4.5 million in the aggregate upon reaching agreed upon regulatory milestones. We also paid AstraZeneca \$0.2 million for the transfer of technology in 2004. We are obligated to pay royalties on a country-by-country basis on annual sales of cangrelor, and on any sublicense income earned, until the later of the duration of the licensed patent rights which are necessary to manufacture, use or sell cangrelor in a country ten years from our first commercial sale of cangrelor in such country.

Under the agreement, we are obligated to use commercially reasonable efforts to develop, market and sell cangrelor. We were also required to file an NDA for cangrelor by December 31, 2009. Because we did not satisfy this requirement, AstraZeneca has the right to terminate our rights under the license to develop, market and sell cangrelor in the United States, subject to conducting discussions with us regarding reasonable solutions to the delay in the filing. We are currently discussing with AstraZeneca this matter and our proposed Phase 3 clinical trials for cangrelor.

The licenses and rights under the agreement remain in force on a country-by-country basis until we cease selling cangrelor in such country or the agreement is otherwise terminated. We may terminate the agreement upon 30 days' written notice, unless AstraZeneca, within 20 days of having received our notice, requests that we enter into good faith discussions to redress our concerns. If we cannot reach a mutually agreeable solution with AstraZeneca within three months of the commencement of such discussions, we may then terminate the agreement upon 90 days' written notice. Either party may terminate the agreement for material breach upon 60 days' prior written notice if the breach is not cured within such 60 days.



*Oritavancin.* As a result of our acquisition of Targanta, we are a party to a license agreement with Eli Lilly through our Targanta subsidiary. Under the terms of the agreement, we have exclusive worldwide rights to patents and other intellectual property related to oritavancin and other compounds claimed in the licensed patent rights. We are required to make payments to Eli Lilly upon reaching specified regulatory and sales milestones. In addition, we are obligated to pay royalties based on net sales of products containing oritavancin or the other compounds in any jurisdiction in which we hold license rights to a valid patent. The royalty rate due to Eli Lilly on sales increases as annual sales of these products increase.

We are obligated to use commercially reasonable efforts to obtain and maintain regulatory approval for oritavancin in the United States and to commercialize oritavancin in the United States. If we breach that obligation, Eli Lilly may terminate our license in the United States, license rights to oritavancin could revert to Eli Lilly and we would lose our rights to develop and commercialize oritavancin. The license rights under the agreement remain in force, on a country-by-country basis, until there is no valid patent in such country and our obligation to pay royalties ceases in that country. Either party may terminate the agreement upon an uncured material breach by the other party. In addition, either party may terminate the agreement upon the other party's insolvency or bankruptcy.

*ApoA-I Milano.* In December 2009, we licensed exclusive worldwide rights to ApoA-I Milano from Pfizer. Under the terms of the agreement, we have rights under specified Pfizer patents, patent applications and know-how to develop, manufacture and commercialize products containing ApoA-I Milano and improvements to the compound. We paid Pfizer \$10 million upon entering into the agreement and agreed to pay up to an aggregate of \$410 million upon the achievement of specified clinical, regulatory and sales milestones. We are obligated to make royalty payments, which are payable on a product-by-product and country-by-country basis, until the latest of the expiration of the last patent or patent application covering ApoA-I Milano, the expiration of any market exclusivity and a specified period of time after the first commercial sale of ApoA-I Milano. In addition, we agreed to pay Pfizer a portion of the consideration received by us or our affiliates in connection with sublicenses. Under the agreement, we may sublicense the intellectual property to third parties, provided that we have complied with Pfizer's right of first negotiation and, in the case of sublicenses to unaffiliated third parties in certain countries, provided that we first obtain Pfizer's consent. We, either directly or through our affiliates or sublicensees, have also agreed to use commercially reasonable efforts to develop at least one product with ApoA-I Milano and to commercialize any approved products related thereto.

The agreement expires upon the expiration of our obligation to pay royalties under the agreement. Either party may terminate the agreement upon an uncured material breach by the other party. In addition, either party may terminate the agreement upon the other party's insolvency or bankruptcy or if the other party is subject to a force majeure event. We may terminate this agreement in its entirety, or on a product-by-product basis, at any time and for any reason upon prior written notice. Pfizer may terminate this agreement if we notify them that we intend to permanently abandon the development, manufacture and commercialization of the products or if we otherwise cease, for a specified period of time, to use commercially reasonable efforts to develop, manufacture and commercialize, as applicable, at least one product.

We also paid \$7.5 million to third parties in connection with the license and agreed to make additional payments to them of up to \$12.0 million in the aggregate upon the achievement of specified development milestones and continuing payments on sales of ApoA-I Milano.

*Ready-to-Use Argatroban.* In September 2009, we licensed marketing rights in the United States and Canada to an intravenous, ready-to-use formulation of Argatroban from Eagle. Under the license agreement, we paid Eagle a \$5.0 million technology license fee. We also agreed to pay additional approval and commercialization milestones up to a total of \$15.0 million and royalties on net sales of the ready-to-use formulation. The license agreement expires at the later of the termination of the development plan under the agreement or as long as we exploit the products under the agreement. Either party may terminate the agreement for material breach by the other party, if the material breach is not cured after receipt of written notice within 30 days or up to 60 days if the breaching party gives notice that it is in good faith attempting to cure the breach. In addition, we have the right to terminate the agreement at any time after September 24, 2010 upon 60 days' notice.

## Customers

In March 2007, we began selling Angiomax in the United States to our sole source distributor, ICS, and we began selling Cleviprex to ICS in September 2008. ICS accounted for 96% of our net revenue in both 2009 and 2008. At December 31, 2009, amounts due from ICS represented approximately \$33.8 million, or 94%, of gross accounts receivable. At December 31, 2008, amounts due from ICS represented approximately \$32.4 million, or 90%, of gross accounts receivable. From January 2007 through March 2007, we sold Angiomax primarily to a limited number of domestic wholesalers with distribution centers located throughout the United States and to several international distributors. In 2007, ICS accounted for 82% of our net revenue. At December 31, 2007, amounts due from the sole source distributor to us represented approximately \$25.3 million, or 93%, of our gross accounts receivable.

## Government Regulation

Government authorities in the United States and other countries extensively regulate the testing, manufacturing, labeling, safety advertising, promotion, storage, sales, distribution, export and marketing, among other things, of our products and product candidates. In the United States, the FDA regulates drugs, including biologic drugs, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and their implementing regulations. We cannot market a drug until we have submitted an application for marketing authorization to the FDA, and the FDA has approved it. Both before and after approval is obtained, violations of regulatory requirements may result in various adverse consequences, including, among other things, untitled letters, warning letters, fines and other monetary penalties, the FDA's delay in approving or refusal to approve a product, product recall or seizure, suspension or withdrawal of an approved product from the market, interruption of production, operating restrictions, injunctions and the imposition of civil or criminal penalties. The steps required before a drug may be approved by the FDA and marketed in the United States include:

- pre-clinical laboratory tests, animal studies and formulation studies;
- submission to the FDA of an investigational new drug application, or IND, for human clinical testing, which must become effective before human clinical trials may begin;
- adequate and well-controlled clinical trials to establish the safety and efficacy of the drug for each indication;
- submission to the FDA of an NDA or biologics license approval, or BLA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practices, or cGMP; and
- FDA review and approval of the NDA or BLA.

Pre-clinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. The results of the pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA puts the trial on clinical hold because of concerns or questions about issues such as the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Submission of an IND does not necessarily result in the FDA allowing clinical trials to commence. In addition, the FDA may impose a clinical hold on an ongoing clinical trial if, for example, safety concerns arise, in which case the trial cannot recommence without FDA's authorization.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring subject safety, and the effectiveness criteria, or endpoints, to be evaluated. Each protocol must be submitted to the FDA as part of the IND and the FDA may or may not

allow that trial to proceed. Each trial also must be reviewed and approved by an independent Institutional Review Board, or IRB, before it can begin.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Phase 1 usually involves the initial introduction of the investigational drug into people to evaluate its safety, dosage tolerance, pharmacodynamics, and, if possible, to gain an early indication of its effectiveness. Phase 2 usually involves trials in a limited patient population to:

- evaluate dosage tolerance and appropriate dosage;
- identify possible adverse effects and safety risks; and
- evaluate preliminarily the efficacy of the drug for specific indications.

Phase 3 trials usually further evaluate clinical efficacy and test further for safety by administering the drug in its final form in an expanded patient population. We cannot guarantee that Phase 1, Phase 2 or Phase 3 testing will be completed successfully within any specified period of time, if at all. Furthermore, we, the IRB, or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Assuming successful completion of the required clinical testing, the results of the pre-clinical studies and of the clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA or BLA requesting approval to market the product for one or more indications. Before approving an application, the FDA usually will inspect the facility or the facilities at which the drug is manufactured, and will not approve the product unless cGMP compliance is satisfactory. If the FDA determines the application or manufacturing facilities are not acceptable, the FDA may outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. As a condition of approval of an application, the FDA may require postmarket testing and surveillance to monitor the drug's safety or efficacy. After approval, certain changes to the approved product, such as adding new indications, manufacturing changes, or additional labeling claims, are subject to further FDA review and approval before the changes can be implemented. The testing and approval process requires substantial time, effort and financial resources, and we cannot be sure that any approval will be granted on a timely basis, if at all.

After the FDA approves a product, we, our suppliers, and our contract manufacturers must comply with a number of post-approval requirements. For example, holders of an approved NDA or BLA are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, we and our contract manufacturers must continue to expend time, money, and effort to maintain compliance with cGMP and other aspects of regulatory compliance. In addition, discovery of problems such as safety problems may result in changes in labeling or restrictions on a product manufacturer, or NDA or BLA holder, including removal of the product from the market.

We use and will continue to use third-party manufacturers to produce our products in clinical and commercial quantities, and we cannot be sure that future FDA inspections will not identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product may result in restrictions on a product, manufacturer, or holder of an approved NDA or BLA, including withdrawal of the product from the market. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

After FDA marketing exclusivity expires for an approved drug product, the drug product may be eligible for submission by other parties of applications for approval that require less information than the NDAs and BLAs described above. The FDA may approve an ANDA if the product is the same in important respects as a

listed drug, such as a drug with an effective FDA approval, or the FDA has declared it suitable for an ANDA submission. In these situations, applicants must submit studies showing that the product is bioequivalent to the listed drug, meaning that the rate and extent of absorption of the drug does not show a significant difference from the rate and extent of absorption of the listed drug. Conducting bioequivalence studies is generally less time-consuming and costly than conducting pre-clinical and clinical trials necessary to support an NDA or BLA. A number of ANDAs have been filed with respect to Angiomax. The regulations governing marketing exclusivity and patent protection are complex, and until the outcomes of our effort to extend the patent term and our patent infringement litigation we may not know the disposition of such ANDA submissions.

### *Foreign Regulations*

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application, or CTA, must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with Good Clinical Practices, or GCPs, and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug or biological product under European Union regulatory systems, we must submit a marketing authorization application. The application used to file the NDA or BLA in the United States is similar to that required in Europe, with the exception of, among other things, country-specific document requirements.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Drugs can be authorized in the European Union by using either the centralized authorization procedure or national authorization procedures.

*Centralized EMEA Procedure.* The EMEA implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the European Union. This procedure results in a single marketing authorization issued by the EMEA that is valid across the European Union, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human medicines that are derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines.

For drugs that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMEA, as long as the drug concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

*National EMEA Procedures.* There are also two other possible routes to authorize medicinal products outside the scope of the centralized procedure:

- *Decentralised procedure.* Using the decentralised procedure, an applicant may apply for simultaneous authorization in more than one European Union country of medicinal products that have not yet been authorized in any European Union country and that do not fall within the mandatory scope of the centralised procedure.
- *Mutual recognition procedure.* In the mutual recognition procedure, a medicine is first authorized in one European Union member state, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

## **Research and Development**

Our research and development expenses totaled \$117.6 million in 2009, \$105.7 million in 2008 and \$77.3 million in 2007.

## **Employees**

We believe that our success depends greatly on our ability to identify, attract and retain capable employees. We have assembled a management team with significant experience in drug development and commercialization. In January 2010 and February 2010, we implemented workforce reductions in our office-based and field-based functions, eliminating a total of 72 positions with us. We implemented these reductions to improve efficiencies and better align our costs and structures for the future. Following these reductions, as of February 15, 2010, we employed 462 persons worldwide. Our employees are not represented by any collective bargaining unit, and we believe our relations with our employees are good.

## **Segments and Geographic Information**

We have one reporting segment. For information regarding revenue and other information regarding our results of operations, including geographic segment information, for each of our last three fiscal years, please refer to our consolidated financial statements and note 20 to our consolidated financial statements, which are included in Item 8 of this annual report, and Management's Discussion and Analysis of Financial Condition and Results of Operations included in Item 7 of this annual report.

## **Available Information**

Our Internet address is <http://www.themedicinescompany.com>. The contents of our website are not part of this annual report on Form 10-K, and our Internet address is included in this document as an inactive textual reference only. We make our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the Securities and Exchange Commission, or SEC. We were incorporated in Delaware on July 31, 1996.

## **Item 1A. Risk Factors**

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below in addition to the other information included or incorporated by reference in this annual report. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer. In that case, the trading price of our common stock could fall.*

### **Risks Related to Our Financial Results**

#### ***We have a history of net losses and may not maintain profitability on an annual basis***

Except for 2004 and 2006, we have incurred net losses on an annual basis since our inception. As of December 31, 2009, we had an accumulated deficit of approximately \$344.2 million. We expect to make substantial expenditures to further develop and commercialize our products, including costs and expenses associated with clinical trials, nonclinical and preclinical studies, regulatory approvals and commercialization. Although we achieved profitability in 2004 and in 2006, we have not been profitable in any year since 2006. We will likely need to generate significantly greater revenue in future periods to achieve and maintain profitability in light of our planned expenditures. If we are unable to extend the patent term of the principal U.S. patent covering Angiomax beyond March 23, 2010 and our other U.S. patents covering Angiomax are not sufficient to provide market exclusivity for Angiomax in the United States, Angiomax could be subject to generic competition as early as September 23, 2010. In such event, our ability to generate this revenue will be adversely impacted, possibly materially. We may not achieve profitability in future periods or at all, and we may not be able to maintain profitability for any substantial period of time. If we fail to achieve profitability or maintain profitability on a quarterly or annual basis within the time frame expected by investors or securities analysts, the market price of our common stock may decline.

#### ***Our business is very dependent on the commercial success of Angiomax***

Angiomax has accounted for substantially all of our revenue since we began selling this product in 2000. Until the approval of Cleviprex by the FDA in August 2008, Angiomax was our only commercial product. We expect revenues from Angiomax to continue to account for substantially all of our revenues in 2010. The commercial success of Angiomax depends upon:

- the outcome of our efforts to extend the patent term of the principal U.S. patent covering Angiomax and the degree of market exclusivity in the United States provided by our other U.S. patents covering Angiomax;
- the continued acceptance by regulators, physicians, patients and other key decision-makers of Angiomax as a safe, therapeutic and cost-effective alternative to heparin and other products used in current practice or currently being developed;
- our ability to further develop Angiomax for use in additional patient populations and the clinical data we generate to support expansion of the product label;
- the overall number of PCI procedures performed;
- our success in selling and marketing Angiox in Europe;
- the impact of competition from competitive products and generic versions of Angiomax and those competitive products; and
- the extent to which we and our international distributors are successful in marketing Angiomax.

We intend to continue to develop Angiomax for use in additional patient populations. Even if we are successful in expanding the Angiomax label, the expanded label may not result in higher revenue or income on a continuing basis.

As of December 31, 2009, our inventory of Angiomax was \$24.3 million and we had inventory-related purchase commitments to Lonza Braine totaling \$26.1 million for 2010 and \$19.1 million for 2011 for

Angiomax bulk drug substance. If sales of Angiomax were to decline, we could be required to make an allowance for excess or obsolete inventory or increase our accrual for product returns.

***Our revenue has been substantially dependent on our sole source distributor, ICS, and a limited number of domestic wholesalers and international distributors involved in the sale of our products, and such revenue may fluctuate from quarter to quarter based on the buying patterns of such distributor, wholesalers and distribution partners***

We distribute Angiomax and Cleviprex in the United States through a sole source distribution model. Under this model, we sell Angiomax and Cleviprex to our sole source distributor, ICS, which then sells Angiomax and Cleviprex to a limited number of national medical and pharmaceutical wholesalers with distribution centers located throughout the United States and, in certain cases, directly to hospitals. Our revenue from sales of Angiomax in the United States is now exclusively from sales to ICS. We anticipate that our revenue from sales of Cleviprex in the United States will be exclusively from sales to ICS. As a result, we expect that our revenue will continue to be subject to fluctuation from quarter to quarter based on the buying patterns of ICS.

In some countries outside the European Union, we sell Angiomax to international distributors and these distributors then sell Angiomax to hospitals. Our reliance on a small number of distributors for international sales of Angiomax could cause our revenue to fluctuate from quarter to quarter based on the buying patterns of these distributors, regardless of underlying hospital demand.

If inventory levels at ICS or at our international distributors become too high, these distributors may seek to reduce their inventory levels by reducing purchases from us, which could have a materially adverse effect on our revenue in periods in which such purchase reductions occur.

***Failure to achieve our revenue targets or raise additional funds in the future may require us to delay, reduce the scope of, or eliminate one or more of our planned activities***

We expect to devote substantial resources to our research and development efforts and to our sales, marketing and manufacturing programs associated with Angiomax, Cleviprex and our products in development. Our funding requirements to support these efforts and programs depend upon many factors, including:

- the extent to which Angiomax is commercially successful globally;
- the outcome of our efforts to extend the patent term of the principal U.S. patent covering Angiomax and the degree of market exclusivity in the United States provided by our other U.S. patents covering Angiomax;
- the terms of any settlements with Biogen Idec or the two law firms with respect to the principal U.S. patent covering Angiomax and the PTO's denial of our application to extend the term of the patent;
- our ability to resupply the market with Cleviprex and the extent to which Cleviprex is commercially successful in the United States;
- the extent to which we can successfully establish a commercial infrastructure outside the United States;
- the cost of acquisitions or licensing of development-stage products, approved products, or businesses and strategic or licensing arrangements with companies that fit within our growth strategy;
- the progress, level, timing and cost of our research and development activities related to our clinical trials and non-clinical studies with respect to Angiomax, Cleviprex and our products in development;
- the cost and outcomes of regulatory submissions and reviews for approval of Cleviprex outside the United States and New Zealand and of our products in development globally;
- the continuation or termination of third-party manufacturing and sales and marketing arrangements;
- the size, cost and effectiveness of our sales and marketing programs globally;

- the amounts of our payment obligations to third parties as to Angiomax, Cleviprex and our products in development; and
- our ability to defend and enforce our intellectual property rights.

If our existing resources, together with revenues that we generate from sales of our products and other sources, are insufficient to satisfy our funding requirements, or if we determine that raising additional capital would be in our interest and the interests of our stockholders, we may sell equity or debt securities or seek additional financing through other arrangements. Any sale of equity or debt securities may result in dilution to our stockholders. Any debt financing may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. Public or private financing may not be available in amounts or on terms acceptable to us, if at all. If we seek to raise funds through collaboration or licensing arrangements with third parties, we may be required to relinquish rights to products, products in development or technologies that we would not otherwise relinquish or grant licenses on terms that may not be favorable to us. If we are unable to obtain additional financing, we may be required to delay, reduce the scope of, or eliminate one or more of our planned research, development and commercialization activities, which could harm our financial condition and operating results.

### **Risks Related to Commercialization**

#### ***Angiomax competes with all categories of anticoagulant drugs, which may limit the use of Angiomax and adversely affect our revenue***

Due to the incidence and severity of cardiovascular diseases, the market for anticoagulant therapies is large and competition is intense. There are a number of anticoagulant drugs currently on the market, awaiting regulatory approval and in development, including orally administered agents, which we compete with or may compete with in the future. Angiomax competes with these anticoagulant drugs to the extent Angiomax and any of these anticoagulant drugs are approved for the same or similar indications.

We have positioned Angiomax to compete primarily with heparin, platelet inhibitors such as GP IIb/IIIa inhibitors, and treatment regimens combining heparin and GP IIb/IIIa inhibitors. Because heparin is inexpensive and has been widely used for many years, physicians and medical decision-makers may be hesitant to adopt Angiomax instead of heparin. GP IIb/IIIa inhibitors that Angiomax competes with include ReoPro from Eli Lilly and Johnson & Johnson/Centocor, Inc., Integrilin from Schering-Plough Corporation, and Aggrastat from Iroko Pharmaceuticals, LLC and MediCure Inc. GP IIb/IIIa inhibitors are widely used and some physicians believe they offer superior efficacy in high risk patients. Physicians may choose to use heparin combined with GP IIb/IIIa inhibitors due their years of experience with this combination therapy and reluctance to change existing hospital protocols and pathways.

Angiomax may compete with other anticoagulant drugs for the use of hospital financial resources. For example, many U.S. hospitals receive a fixed reimbursement amount per procedure for the angioplasties and other treatment therapies they perform. As this amount is not based on the actual expenses the hospital incurs, hospitals may choose to use either Angiomax or other anticoagulant drugs but not necessarily several of the drugs together.

In addition, if we are unable to extend the patent term of the principal U.S. patent covering Angiomax beyond March 23, 2010 or to maintain our market exclusivity for Angiomax in the United States through enforcement of our other U.S. patents covering Angiomax, Angiomax could be subject to generic competition as early as September 23, 2010. Competition from generic equivalents that would be sold at a price that is less than the price at which we currently sell Angiomax could have a material adverse impact on our financial condition and operating results.

#### ***Cleviprex competes with all categories of intravenous antihypertensive, or IV-AHT, drugs, which may limit the use of Cleviprex and adversely affect our revenue***

Because different IV-AHT drugs act in different ways on the factors contributing to elevated blood pressure, physicians have many therapeutic options to reduce acutely elevated blood pressure.



We have positioned Cleviprex as an improved alternative drug for selected patient types with acute, severe hypertension. Since all other IV-AHT drugs are available as inexpensive generics, Cleviprex must demonstrate compelling advantages in efficacy, convenience, tolerability and/or safety to compete with these drugs. We may also need to demonstrate that Cleviprex will save the hospital resources in other areas such as length of stay and other resource utilization to become commercially successful. Because generic therapies are inexpensive and have been widely used for many years, physicians and decision-makers for hospital resource allocation may be hesitant to adopt Cleviprex and fail to recognize the value delivered through a newer agent that offers precise blood pressure control.

Hospitals establish formularies, which are lists of drugs approved for use in the hospital. If a drug is not included on the formulary, the ability of our sales representatives to promote the drug may be limited or denied. Hospital formularies may also limit the number of IV-AHT drugs in each drug class. If we fail to secure and maintain formulary inclusion for Cleviprex on favorable terms or are significantly delayed in doing so, we will have difficulty achieving market acceptance of Cleviprex and our business could be materially adversely affected.

***We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do***

Our industry is highly competitive. Our success will depend on our ability to acquire or license, and then develop, products and apply technology, as well as our ability to establish and maintain markets for our products. Competitors in the United States and other countries include major pharmaceutical companies, specialized pharmaceutical companies and biotechnology firms, universities and other research institutions. Many of our competitors have substantially greater research and development capabilities and experience, and greater manufacturing, marketing and financial resources, than we do. Accordingly, our competitors may develop or license products or other novel technologies that are more effective, safer, more convenient or less costly than existing products or technologies or products or technologies that are being developed by us or may obtain regulatory approvals for products more rapidly than we are able. Technological developments by others may render our products or products in development noncompetitive. We may not be successful in establishing or maintaining technological competitiveness.

***If physicians, patients and other key decision-makers do not accept clinical data from trials of Angiomax and Cleviprex, then sales of Angiomax and Cleviprex may be adversely affected***

We believe that the near-term commercial success of Angiomax and Cleviprex will depend in part upon the extent to which physicians, patients and other key decision-makers accept the results of clinical trials of Angiomax and Cleviprex. For example, since the original results of REPLACE-2 were announced in 2002, additional hospitals have granted Angiomax formulary approval and hospital demand for the product has increased. These trends, however, may not continue. Some commentators have challenged various aspects of the trial design of REPLACE-2, the conduct of the study and the analysis and interpretation of the results from the study. Similarly, physicians, patients and other key decision-makers may not accept the results of the ACUTY and HORIZONS AMI trials. The FDA, in denying our sNDA for an additional dosing regimen in the treatment of ACS initiated in the emergency department, indicated that the basis of its decision involved the appropriate use and interpretation of non-inferiority trials such as our ACUTY trial. If physicians, patients and other key decision-makers do not accept clinical trial results, adoption and continued use of Angiomax and Cleviprex may suffer, and our business will be materially adversely affected.

***If the number of PCI procedures performed decreases, sales of Angiomax may be negatively impacted***

We believe that as a result of data from a clinical trial that was published in March 2007 in the New England Journal of Medicine entitled "Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation," or "COURAGE", and the controversy regarding the use of drug-eluting stents, the number of PCI procedures performed in the United States declined in 2007. PCI procedure volume increased in 2008 from 2007 levels, but did not return to the level of PCI procedures performed prior to the 2007 decline and declined again in 2009 from 2008 levels. We believe that the 2009 decline was due, in part, to economic pressures on our hospital customers in 2009. The decline in the number of PCI procedures has had a direct impact on our

net revenues. PCI procedure volume might further decline and might not return to its previous levels. Because PCI procedures are the primary procedures during which Angiomax is used, a further decline in the number of procedures may negatively impact sales of Angiomax.

***If we are unable to successfully expand our business infrastructure and develop our global operations, our ability to generate future product revenue will be adversely affected***

To support the global sales and marketing of Angiomax, Cleviprex and our product candidates in development if and when they are approved for sale and marketed outside the United States, we are developing our business infrastructure globally, with European operations being our initial focus. If we are unable to expand our global operations successfully and in a timely manner, the growth of our business may be limited and our business, operating results and financial condition may be harmed. Such expansion may be more difficult, more expensive or take longer than we anticipate, and we may not be able to successfully market and sell our products globally.

Future rapid expansion could strain our operational, human and financial resources. In order to manage expansion, we must:

- continue to improve operating, administrative, and information systems;
- accurately predict future personnel and resource needs to meet contract commitments;
- track the progress of ongoing projects; and
- attract and retain qualified management, sales, professional, scientific and technical operating personnel.

If we do not take these actions and are not able to manage our global business, then our global operations may be less successful than anticipated, and we may be required to allocate additional resources to the expanded business, which we would have otherwise allocated to another part of our business.

***The success of our global operations may be adversely affected by international risks and uncertainties. If these operations are not successful, our results of operations and financial position could be adversely affected.***

Our future profitability will depend in part on our ability to grow and ultimately maintain our product sales in foreign markets, particularly in Europe. In addition, with our acquisitions of Curacyte Discovery and Targanta, we are conducting research and development activities in Germany and Canada. These foreign operations subject us to additional risks and uncertainties, particularly because we have limited experience in marketing, servicing and distributing our products or otherwise operating our business outside of the United States. These risks and uncertainties include:

- our customers' ability to obtain reimbursement for procedures using our products in foreign markets;
- the burden of complying with complex and changing foreign legal, tax, accounting and regulatory requirements;
- language barriers and other difficulties in providing customer support and service;
- longer accounts receivable collection times;
- significant currency fluctuations;
- reduced protection of intellectual property rights in some foreign countries; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Our foreign operations could also be adversely affected by export license requirements, the imposition of governmental controls, political and economic instability, trade restrictions, changes in tariffs and difficulties in staffing and managing foreign operations. In addition, we are subject to the Foreign Corrupt Practices Act, any violation of which could create a substantial liability for us and also cause a loss of reputation in the market.

***Our ability to generate future product revenue will be affected by reimbursement and drug pricing***

Acceptable levels of coverage and reimbursement of drug treatments by government payers such as Medicare and Medicaid programs, private health insurers and other organizations will have a significant effect on our ability to successfully commercialize our product candidates. Reimbursement in the United States, Europe or elsewhere may not be available for any products we may develop or, if already available, may be decreased in the future. We may not get reimbursement or reimbursement may be limited if government payers, private health insurers and other organizations are influenced by the prices of existing drugs in determining whether our products will be reimbursed and at what levels. For example, the availability of numerous generic antibiotics at lower prices than branded antibiotics, such as oritavancin, if it were approved for commercial sale, could substantially affect the likelihood of reimbursement and the level of reimbursement for oritavancin. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize our products, or may not be able to obtain a satisfactory financial return on our products.

In certain countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals and the level of reimbursement are subject to governmental control. In some countries, it can take an extended period of time to establish and obtain reimbursement, and reimbursement approval may be required at the individual patient level, which can lead to further delays. In addition, in some countries, it may take an extended period of time to collect payment even after reimbursement has been established.

Third-party payers increasingly are challenging prices charged for medical products and services. Also, the trend toward managed health care in the United States and the changes in health insurance programs may result in lower prices for pharmaceutical products. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could significantly impact our business. Cost-cutting measures that the U.S. government, state legislatures, and the private sector are instituting and the effect of any health care reform could materially adversely affect our ability to sell Angiomax, Cleviprex and any products that are successfully developed by us and approved by regulators. These cost-cutting measures include:

- controls on government-funded reimbursement for drugs;
- new or increased obligations to pay prescription drug rebates to government health care programs;
- limitations on or challenges to the pricing of drug; and
- controls on healthcare providers.

Moreover, we are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on our business.

***If we do not comply with federal, state and foreign laws and regulations relating to the health care business, we could face substantial penalties***

We and our customers are subject to extensive regulation by the federal government, and the governments of the states and foreign countries in which we may conduct our business. In the United States, the laws that directly or indirectly affect our ability to operate our business include the following:

- the Federal Anti-Kickback Law, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service for which payment may be made under federal health care programs such as Medicare and Medicaid;
- other Medicare laws and regulations that prescribe the requirements for coverage and payment for services performed by our customers, including the amount of such payment;
- the Federal False Claims Act, which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;

- the Federal False Statements Act, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with delivery of or payment for health care benefits, items or services; and
- various state laws that impose similar requirements and liability with respect to state healthcare reimbursement and other programs.

If our operations are found to be in violation of any of the laws and regulations described above or any other law or governmental regulation to which we or our customers are or will be subject, we may be subject to civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations. Similarly, if our customers are found to be non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on us. Any penalties, damages, fines, curtailment or restructuring of our operations would adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation.

***If we are unable to obtain insurance at acceptable costs and adequate levels or otherwise protect ourselves against potential product liability claims, we could be exposed to significant liability***

Our business exposes us to potential product liability risks which are inherent in the testing, manufacturing, marketing and sale of human healthcare products. Product liability claims might be made by patients in clinical trials, consumers, health care providers or pharmaceutical companies or others that sell our products. These claims may be made even with respect to those products that are manufactured in licensed and regulated facilities or otherwise possess regulatory approval for commercial sale.

These claims could expose us to significant liabilities that could prevent or interfere with the development or commercialization of our products. Product liability claims could require us to spend significant time and money in litigation or pay significant damages. With respect to our commercial sales and our clinical trials, we are covered by product liability insurance in the amount of \$20.0 million per occurrence and \$20.0 million annually in the aggregate on a claims-made basis. This coverage may not be adequate to cover any product liability claims.

As we continue to commercialize our products, we may wish to increase our product liability insurance. Product liability coverage is expensive. In the future, we may not be able to maintain or obtain such product liability insurance on reasonable terms, at a reasonable cost or in sufficient amounts to protect us against losses due to product liability claims.

## **Risks Related to Regulatory Matters**

***If we do not obtain regulatory approvals for our product candidates, we will not be able to market our product candidates and our ability to generate additional revenue could be materially impaired***

We must obtain approval from the FDA in order to sell our product candidates in the United States and from foreign regulatory authorities in order to sell our product candidates in other countries. Except for Angiomax in the United States, Europe and other countries and Cleviprex in the United States and New Zealand, we do not have any other product approved for sale in the United States or any foreign market. Obtaining regulatory approval is uncertain, time-consuming and expensive. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product commercially non-viable. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the regulatory authorities for each therapeutic indication to establish the product's safety and efficacy. If we are unable to submit the necessary data and information, for example, because the results of clinical trials are not favorable, or if the applicable regulatory authority delays reviewing or does not

approve our applications, we will be unable to obtain regulatory approval. Delays in obtaining or failure to obtain regulatory approvals may:

- delay or prevent the successful commercialization of any of our product candidates;
- diminish our competitive advantage; and
- defer or decrease our receipt of revenue.

The regulatory review and approval process to obtain marketing approval for a new drug or indication takes many years and requires the expenditure of substantial resources. This process can vary substantially based on the type, complexity, novelty and indication of the product candidate involved. The regulatory authorities globally have substantial discretion in the approval process and may refuse to accept any application or may decide that data is insufficient for approval and require additional pre-clinical, clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. For example, the FDA issued a complete response letter to Targanta in December 2008 before it was acquired by us with respect to the oritavancin NDA indicating that the FDA could not approve the NDA in its present form and that it would be necessary for Targanta to perform an additional adequate and well-controlled study to demonstrate the safety and efficacy of oritavancin in patients with ABSSSI before the application could be approved.

***We cannot expand the indications for which we are marketing Angiomax unless we receive regulatory approval for each additional indication. Failure to expand these indications will limit the size of the commercial market for Angiomax***

The FDA has approved Angiomax for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing PCI and patients undergoing PCI with or at risk of HIT/HITTS. Angiox is approved for patients undergoing PCI, for adult patients with ACS and for the treatment of STEMI patients undergoing primary PCI in the European Union. One of our key objectives is to expand the indications for which Angiomax is approved. In order to market Angiomax for expanded indications, we will need to conduct appropriate clinical trials, obtain positive results from those trials and obtain regulatory approval for such proposed indications. Obtaining regulatory approval is uncertain, time-consuming and expensive. The regulatory review and approval process to obtain marketing approval for a new indication can take many years and require the expenditure of substantial resources. This process can vary substantially based on the type, complexity, novelty and indication of the product candidate involved. The regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that any data submitted is insufficient for approval and require additional pre-clinical, clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a new indication product candidate.

For example, in 2006 we received a non-approvable letter from the FDA in connection with our application to market Angiomax in patients with or at risk of HIT/HITTS undergoing cardiac surgery. While we have indicated to the FDA that we are evaluating potential next steps, the FDA may require additional studies which may require the expenditure of substantial resources. Even if any such studies are undertaken, we might not be successful in obtaining regulatory approval for this indication in a timely manner or at all. In addition, in May 2008, we received a non-approvable letter from the FDA with respect to an sNDA that we submitted to the FDA seeking approval of an additional indication for Angiomax for the treatment of patients with ACS in the emergency department. In its letter, the FDA indicated that the basis of their decision involved the appropriate use and interpretation of non-inferiority trials, including the ACUITY trial. We disagree with the FDA on these issues and continue to evaluate how to respond to the FDA's views on the ACUITY trial. We might not be successful in obtaining regulatory approval for these indications or any other indications in a timely manner or at all. If we are unsuccessful in expanding the Angiomax product label, the size of the commercial market for Angiomax will be limited.

***Clinical trials of product candidates are expensive and time-consuming, and the results of these trials are uncertain***

Before we can obtain regulatory approvals to market any product for a particular indication, we will be required to complete pre-clinical studies and extensive clinical trials in humans to demonstrate the safety and efficacy of such product for such indication.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in pre-clinical testing or early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. An unexpected result in one or more of our clinical trials can occur at any stage of testing. For example, in May 2009 we discontinued enrollment in our Phase 3 CHAMPION clinical trial program of cangrelor in patients undergoing PCI after receiving a letter from the clinical program's independent Interim Analysis Review Committee that stated that the CHAMPION-PLATFORM trial would not meet the goal of demonstrating persuasive evidence of clinical effectiveness that could form the basis for regulatory approval.

We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent us from receiving regulatory approval or commercializing our products, including:

- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials which even if undertaken cannot ensure we will gain approval;
- data obtained from pre-clinical testing and clinical trials may be subject to varying interpretations, which could result in the FDA or other regulatory authorities deciding not to approve a product in a timely fashion, or at all;
- the cost of clinical trials may be greater than we currently anticipate;
- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we, or the FDA or other regulatory authorities, might suspend or terminate a clinical trial at any time on various grounds, including a finding that participating patients are being exposed to unacceptable health risks. For example, we have in the past voluntarily suspended enrollment in one of our clinical trials to review an interim analysis of safety data from the trial; and
- the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

The rate of completion of clinical trials depends in part upon the rate of enrollment of patients. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments. In particular, the patient population targeted by some of our clinical trials may be small. Delays in patient enrollment in any of our current or future clinical trials may result in increased costs and program delays.

***If we or our contract manufacturers fail to comply with the extensive regulatory requirements to which we, our contract manufacturers and our products are subject, our products could be subject to restrictions or withdrawal from the market and we could be subject to penalties***

The testing, manufacturing, labeling, safety, advertising, promotion, storage, sales, distribution, export and marketing, among other things, of our products, both before and after approval, are subject to extensive regulation by governmental authorities in the United States, Europe and elsewhere throughout the world. Both before and after approval of a product, quality control and manufacturing procedures must conform to current good manufacturing practice, or cGMP. Regulatory authorities, including the FDA, periodically inspect manufacturing facilities to assess compliance with cGMP. Our failure or the failure of our contract

manufacturers to comply with the laws administered by the FDA, the European Medicines Agency or other governmental authorities could result in, among other things, any of the following:

- delay in approving or refusal to approve a product;
- product recall or seizure;
- suspension or withdrawal of an approved product from the market;
- interruption of production;
- operating restrictions;
- untitled or warning letters;
- injunctions;
- fines and other monetary penalties;
- the imposition of civil or criminal penalties; and
- unanticipated expenditures.

#### **Risks Related to our Dependence on Third Parties for Manufacturing, Research and Development, and Distribution Activities**

*We depend on single source suppliers for the production of bulk drug substance for Angiomax, Cleviprex and our other products in development and a limited number of suppliers to carry out all fill-finish activities*

We do not manufacture any of our products and do not plan to develop any capacity to manufacture them. We currently obtain all bulk drug substance for each of Angiomax, Cleviprex and our products in development from single source suppliers, and rely on a limited number of manufacturers to carry out all fill-finish activities for each of Angiomax, Cleviprex and our products in development.

We do not currently have alternative sources for production of bulk drug substance or to carry out fill-finish activities. In the event that any of our third-party manufacturers is unable or unwilling to carry out its respective manufacturing or supply obligations or terminates or refuses to renew its arrangements with us, we may be unable to obtain alternative manufacturing or supply, or obtain such manufacturing or supply on commercially reasonable terms or on a timely basis. In addition, we purchase finished drug product from a number of our third-party manufacturers under purchase orders. In such cases, the third-party manufacturers have made no commitment to supply the drug product to us on a long-term basis and could reject a new purchase order. Only a limited number of manufacturers are capable of manufacturing Angiomax, Cleviprex and our products in development. Moreover, consolidation within the pharmaceutical manufacturing industry could further reduce the number of manufacturers capable of producing our products, or otherwise affect our existing contractual relationships. If we were required to transfer manufacturing processes to other third-party manufacturers and we were able to identify an alternative manufacturer, we would still need to satisfy various regulatory requirements, which could cause us to experience significant delays in receiving an adequate supply of Angiomax, Cleviprex and our products in development. Moreover, we may not be able to transfer processes that are proprietary to the manufacturer. Any delays in the manufacturing process may adversely impact our ability to meet commercial demands for Angiomax or Cleviprex on a timely basis, which could reduce our revenue, and supply product for clinical trials of Angiomax, Cleviprex and our products in development, which could affect our ability to complete clinical trials on a timely basis or at all.

*If third parties on whom we rely to manufacture and support the development and commercialization of our products do not fulfill their obligations, the development and commercialization of our products may be terminated or delayed, and the costs of development and commercialization may increase.*

Our development and commercialization strategy involves entering into arrangements with corporate and academic collaborators, contract research organizations, distributors, third-party manufacturers, licensors,

licensees and others to conduct development work, manage or conduct our clinical trials, manufacture our products and market and sell our products outside of the United States. We do not have the expertise or the resources to conduct many of these activities on our own and, as a result, are particularly dependent on third parties in many areas.

We may not be able to maintain our existing arrangements with respect to the commercialization or manufacture of Angiomax and Cleviprex or establish and maintain arrangements to develop, manufacture and commercialize our products in development or any additional product candidates or products we may acquire on terms that are acceptable to us. Any current or future arrangements for development and commercialization may not be successful. If we are not able to establish or maintain agreements relating to Angiomax, Cleviprex, our products in development or any additional products we may acquire, our results of operations would be materially adversely affected.

Third parties may not perform their obligations as expected. The amount and timing of resources that third parties devote to developing, manufacturing and commercializing our products are not within our control. Our collaborators may develop, manufacture or commercialize, either alone or with others, products and services that are similar to or competitive with the products that are the subject of the collaboration with us. Furthermore, our interests may differ from those of third parties that manufacture or commercialize our products. Our collaborators may reevaluate their priorities from time to time, including following mergers and consolidations, and change the focus of their development, manufacturing or commercialization efforts. Disagreements that may arise with these third parties could delay or lead to the termination of the development or commercialization of our product candidates, or result in litigation or arbitration, which would be time consuming and expensive.

If any third party that manufactures or supports the development or commercialization of our products breaches or terminates its agreement with us, or fails to commit sufficient resources to our collaboration or conduct its activities in a timely manner, or fails to comply with regulatory requirements, such breach, termination or failure could:

- delay or otherwise adversely impact the manufacturing, development or commercialization of Angiomax, Cleviprex, our products in development or any additional products that we may acquire or develop;
- require us to seek a new collaborator or undertake unforeseen additional responsibilities or devote unforeseen additional resources to the manufacturing, development or commercialization of our products; or
- result in the termination of the development or commercialization of our products.

***Use of third-party manufacturers may increase the risk that we will not have appropriate supplies of our products or our product candidates***

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party; and
- the possible termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

Angiomax and Cleviprex and our products in development may compete with products and product candidates of third parties for access to manufacturing facilities. If we are not able to obtain adequate supplies of Angiomax, Cleviprex and our products in development, it will be more difficult for us to compete effectively, market and sell our approved products and develop our products in development.

Our contract manufacturers are subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to evaluate compliance with the FDA's cGMP,



regulations and other governmental regulations and corresponding foreign standards. We cannot be certain that our present or future manufacturers will be able to comply with cGMP regulations and other FDA regulatory requirements or similar regulatory requirements outside the United States. We do not control compliance by our contract manufacturers with these regulations and standards. Failure of our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines and other monetary penalties, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, interruption of production, warning letters, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of Angiomax, Cleviprex and our products in development.

On December 16, 2009, we conducted a voluntary recall of 11 lots of Cleviprex due to the presence of visible particulate matter that was deposited at the bottom of some vials and was observed in such vials during a routine annual inspection. We are scheduled to extend our voluntary recall in March 2010 to include four additional manufactured lots of Cleviprex that now also show visible particulate matter that was deposited at the bottom of some vials. As a result, we are not able to supply the market at this time with existing inventory or using the current manufacturing method. We are cooperating with the FDA and our contract manufacturer on these recalls and to remedy the problem at the manufacturing site. If the manufacturing problem is remedied, we anticipate being able to supply the market in the second quarter of 2010. If the problem is not remedied, we may pursue production of drug product using other approaches, which could delay the supply of Cleviprex up to 18 months. Any delay in resupplying the market with Cleviprex would reduce our revenues.

***In order to satisfy some regulatory authorities, we may need to reformulate the way in which our oritavancin bulk drug substance is created to remove animal source product, which may delay marketing approval of our products and increase our costs***

Oritavancin bulk drug substance is manufactured using animal-sourced products, namely porcine-sourced products. Some non-U.S. regulatory authorities have historically objected to the use of animal-sourced products, particularly bovine-sourced products, during the preparation of finished drug product. As a result and in order to better position oritavancin for approval in foreign jurisdictions, under our agreement with Abbott, we and Abbott are seeking to develop a manufacturing process for oritavancin bulk drug substance that does not rely on the use of any animal-sourced products.

If we are unable to develop a manufacturing process for oritavancin bulk drug substance that does not rely on the use of animal-sourced product, we may be unable to receive regulatory approval for oritavancin in some foreign jurisdictions, which would likely have a negative impact on our ability to achieve our business objectives as to oritavancin.

***If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages***

As a result of our acquisitions of Curacyte Discovery and Targanta, we now conduct research and development activities that involve the controlled use of potentially hazardous substances, including chemical, biological and radioactive materials and viruses. In addition, our operations produce hazardous waste products. Federal, state and local laws and regulations in each of the United States, Canada and Germany govern the use, manufacture, storage, handling and disposal of hazardous materials. We may incur significant additional costs to comply with applicable laws in the future. Also, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We have only limited insurance for liabilities arising from hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may restrict our research, development and production efforts, which could harm our business, operating results and financial condition.

## **Risks Related to Our Intellectual Property**

***If we are unable to extend the patent term of the principal U.S. patent covering Angiomax or to maintain market exclusivity for Angiomax in the United States through the enforcement of our other U.S. patents covering Angiomax, then Angiomax could be subject to generic competition as early as September 2010. Generic competition for Angiomax would have an adverse effect on our business, financial condition and results of operations***

The principal U.S. patent covering Angiomax expires on March 23, 2010. We will then have a six-month period of market exclusivity for Angiomax in the United States which will expire on September 23, 2010 due to our study of Angiomax in the pediatric setting. We applied, under the Hatch-Waxman Act, for an extension of the term of the principal U.S. patent for Angiomax. The PTO rejected our application because in its view the application was not timely filed. Since 2002, we have filed requests with the PTO for reconsideration of the denial of the application, but in April 2007 and again in January 2010, the PTO denied our application for patent term extension. In January 2010, we brought suit against the PTO, the FDA and the U.S. Department of Health and Human Services seeking to set aside the denial of our application to extend of the term of the principal patent that covers Angiomax. We cannot predict the outcome of this litigation.

On June 23, 2008, the United States House of Representatives passed a bill that, if enacted, would have provided the PTO with discretion to consider patent extension applications filed late unintentionally under the Hatch-Waxman Act. The United States Senate adjourned without considering this bill. Congress may consider legislation similar to that passed by the House in June 2008. However, a bill may not be introduced or enacted or, if it is enacted, the PTO may still not consider our application. We will continue to explore alternatives to extend the term of the patent but we may not be successful in doing so.

In September and October 2009, we were granted two U.S. patents covering Angiomax. We listed both patents in the Orange Book for Angiomax. In October 2009 and January 2010, in response to Paragraph IV Certification Notice letters we received with respect to ANDAs filed with the FDA seeking approval to market generic versions of Angiomax, we filed lawsuits against the ANDA filers alleging patent infringement of the two patents in the U.S. District Court for the District of Delaware. We cannot predict the outcome of these lawsuits.

If we are unable to extend the patent term of the principal U.S. patent covering Angiomax beyond March 23, 2010 or to maintain our market exclusivity for Angiomax in the United States through enforcement of our other U.S. patents covering Angiomax, Angiomax could be subject to generic competition in the United States as early as September 2010. Competition from generic equivalents that would be sold at a price that is less than the price at which we currently sell Angiomax could have a material adverse impact on our business, financial condition and operating results.

***If we breach any of the agreements under which we license rights to products or technology from others, we could lose license rights that are material to our business or be subject to claims by our licensors***

We license rights to products and technology that are important to our business, and we expect to enter into additional licenses in the future. For instance, we have exclusively licensed patents and patent applications relating to Angiomax, Cleviprex and each of our products in development other than CU2010. Under these agreements, we are subject to a range of commercialization and development, sublicensing, royalty, patent prosecution and maintenance, insurance and other obligations.

Any failure by us to comply with any of these obligations or any other breach by us of our license agreements could give the licensor the right to terminate the license in whole, terminate the exclusive nature of the license or bring a claim against us for damages. Any such termination or claim, particularly relating to our agreements with respect to Angiomax, could have a material adverse effect on our financial condition, results of operations, liquidity or business. Even if we contest any such termination or claim and are ultimately successful, our stock price could suffer. In addition, on termination we may be required to license to the licensor any related intellectual property that we developed.

We have entered into an agreement with Biogen Idec, one of our licensors for Angiomax, that suspends the statute of limitations relating to any claims, including claims for damages and/or license termination, that Biogen Idec may bring relating to the PTO's rejection of the application under the Hatch-Waxman Act for an extension of the term of the principal U.S. patent that covers Angiomax on the grounds that, in its view, it was not timely filed. We have also entered into agreements with the law firms involved in the patent extension filing that suspend the statute of limitations on our claims against them for the filing. In the third quarter of 2009, we initiated discussions with the two law firms involved in the patent extension filing of the application under the Hatch-Waxman Act and are currently in related discussions with Biogen Idec and HRI with respect to the possible resolution of the potential claims among the parties. We may not reach an agreement with the parties on acceptable terms to us or at all.

In addition, under our license agreement with AstraZeneca, we were required to file an NDA for cangrelor by December 31, 2009. Because we did not satisfy this requirement, AstraZeneca has the right to terminate our rights under the license to develop, market and sell cangrelor in the United States, subject to conducting discussions with us regarding reasonable solutions to the delay in the filing. We are currently discussing with AstraZeneca this matter and our proposed Phase 3 clinical trials for cangrelor. We may not reach an agreement with AstraZeneca on acceptable terms to us or at all.

***If we are unable to obtain or maintain patent protection for the intellectual property relating to our products, the value of our products will be adversely affected***

The patent positions of pharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual issues. Our success depends significantly on our ability to:

- obtain and maintain U.S. and foreign patents, including defending those patents against adverse claims;
- secure patent term extension for the patents covering our approved products;
- protect trade secrets;
- operate without infringing the proprietary rights of others; and
- prevent others from infringing our proprietary rights.

We may not have any additional patents issued from any patent applications that we own or license. If additional patents are granted, the claims allowed may not be sufficiently broad to protect our technology. In addition, issued patents that we own or license may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection we may have for our products, and we may not be able to obtain patent term extension to prolong the terms of the principal patents covering our approved products. Changes in patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that others have not filed or maintained patent applications for technology used by us or covered by our pending patent applications without our being aware of these applications.

We exclusively licensed patents and patent applications for Angiomax, Cleviprex and each of our other products in development other than CU2010. The U.S. patents licensed by us are currently set to expire at various dates. We plan to file applications for U.S. patent term extension for our products in development upon their approval by the FDA.

We are a party to a number of lawsuits that we brought against pharmaceutical companies that have notified us that they have filed ANDAs seeking approval to market generic versions of Angiomax. We cannot predict the outcome of these lawsuits. During the period in which these matters are pending, the uncertainty of their outcome may cause our stock price to decline. In addition, an adverse result in these matters whether

appealable or not, will likely cause our stock price to decline. Any final, unappealable, adverse result in these matters will likely have a material adverse effect on our results of operations and financial conditions and cause our stock price to decline. In addition, involvement in litigation can be expensive.

***We may be unable to utilize the Chemilog process if Lonza Braine breaches our agreement***

Our agreement with Lonza Braine for the supply of Angiomax bulk drug substance requires that Lonza Braine transfer the technology that was used to develop the Chemilog process to a secondary supplier of Angiomax bulk drug substance or to us or an alternate supplier at the expiration of the agreement, which is currently scheduled to occur in September 2013, but is subject to automatic renewals of consecutive three-year periods unless either party provides notice of non-renewal at least one year prior to the expiration of the initial term or any renewal term. If Lonza Braine fails or is unable to transfer successfully this technology, we would be unable to employ the Chemilog process to manufacture our Angiomax bulk drug substance, which could cause us to experience delays in the manufacturing process and increase our manufacturing costs in the future.

***If we are not able to keep our trade secrets confidential, our technology and information may be used by others to compete against us***

We rely significantly upon unpatented proprietary technology, information, processes and know-how. We seek to protect this information by confidentiality agreements with our employees, consultants and other third-party contractors, as well as through other security measures. We may not have adequate remedies for any breach by a party to these confidentiality agreements. In addition, our competitors may learn or independently develop our trade secrets. If our confidential information or trade secrets become publicly known, they may lose their value to us.

***If we infringe or are alleged to infringe intellectual property rights of third parties, it will adversely affect our business***

Our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents or patent applications under which we do not hold licenses or other rights. Third parties may own or control these patents and patent applications in the United States and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose or be required to seek a license from the third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the PTO and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our products and technology. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

## **Risks Related to Growth and Employees**

***If we fail to acquire and develop additional product candidates or approved products it will impair our ability to grow***

We sell and generate revenue from two products, Angiomax and Cleviprex. In order to generate additional revenue, our business plan is to acquire or license, and then develop and market, additional product candidates or approved products. In 2008 and 2009, for instance, we acquired Curacyte Discovery and Targanta, licensed marketing rights to the ready-to-use formulation of Argatroban and licensed development and commercialization rights to ApoA-I Milano. The success of this growth strategy depends upon our ability to identify, select and acquire or license pharmaceutical products that meet the criteria we have established. Because we have only the limited internal scientific research capabilities that we acquired in our acquisitions of Curacyte Discovery and Targanta, and we do not anticipate establishing additional scientific research capabilities, we are dependent upon pharmaceutical and biotechnology companies and other researchers to sell or license product candidates to us. We need to integrate any acquired products into our existing operations. Integrating any newly acquired business or product could be expensive and time-consuming. We may not be able to integrate any acquired business or product successfully or operate any acquired business profitably. In addition, managing the development of a new product entails numerous financial and operational risks, including difficulties in attracting qualified employees to develop the product.

Any product candidate we acquire or license will require additional research and development efforts prior to commercial sale, including extensive pre-clinical and/or clinical testing and approval by the FDA and corresponding foreign regulatory authorities.

All product candidates are prone to the risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate will not be safe and effective or approved by regulatory authorities. In addition, any approved products that we develop or acquire may not be:

- manufactured or produced economically;
- successfully commercialized; or
- widely accepted in the marketplace.

We have previously acquired or licensed rights to products and, after having conducted development activities, determined not to devote further resources to those products. Any additional products that we acquire or license may not be successfully developed. In addition, proposing, negotiating and implementing an economically viable acquisition or license is a lengthy and complex process. Other companies, including those with substantially greater financial, marketing and sales resources, may compete with us for the acquisition or license of product candidates and approved products. We may not be able to acquire or license the rights to additional product candidates and approved products on terms that we find acceptable, or at all.

***We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants***

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on our ability to attract and retain qualified personnel for the acquisition, development and commercialization activities we conduct or sponsor. If we lose one or more of the members of our senior management, including our Chairman and Chief Executive Officer, Clive A. Meanwell, our Executive Vice President and Chief Financial Officer, Glenn P. Sblendorio, or other key employees or consultants, our ability to implement successfully our business strategy could be seriously harmed. Our ability to replace these key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to acquire, develop and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate such additional personnel.

## **Risks Related to Our Common Stock**

### ***Fluctuations in our operating results could affect the price of our common stock***

Our operating results may vary from period to period based on factors including the amount and timing of sales of Angiomax and Cleviprex, underlying hospital demand for Angiomax and Cleviprex, our customers' buying patterns, the timing, expenses and results of clinical trials, announcements regarding clinical trial results and product introductions by us or our competitors, the availability and timing of third-party reimbursement, including in Europe, sales and marketing expenses and the timing of regulatory approvals. If our operating results do not meet the expectations of securities analysts and investors as a result of these or other factors, the trading price of our common stock will likely decrease.

***Our stock price has been and may in the future be volatile. This volatility may make it difficult for you to sell common stock when you want or at attractive prices***

Our common stock has been and in the future may be subject to substantial price volatility. From January 1, 2008 to March 9, 2010, the last reported sale price of our common stock ranged from a high of \$27.68 per share to a low of \$6.47 per share. The value of your investment could decline due to the effect of any of the following factors upon the market price of our common stock:

- changes in securities analysts' estimates of our financial performance;
- changes in valuations of similar companies;
- variations in our operating results;
- acquisitions and strategic partnerships;
- announcements of technological innovations or new commercial products by us or our competitors;
- disclosure of results of clinical testing or regulatory proceedings by us or our competitors;
- the timing, amount and receipt of revenue from sales of our products and margins on sales of our products;
- governmental regulation and approvals;
- developments in patent rights or other proprietary rights, particularly with respect to the principal U.S. Angiomax patent;
- the terms of any settlement with Biogen Idec or the two law firms with respect to the principal U.S. patent covering Angiomax and the PTO's denial of our application to extend the term of the patent;
- developments or issues with our contract manufacturers;
- changes in our management; and
- general market conditions.

In addition, the stock market has experienced significant price and volume fluctuations, and the market prices of specialty pharmaceutical companies have been highly volatile. Moreover, broad market and industry fluctuations that are not within our control may adversely affect the trading price of our common stock. You must be willing to bear the risk of fluctuations in the price of our common stock and the risk that the value of your investment in our securities could decline.

***Our corporate governance structure, including provisions in our certificate of incorporation and by-laws and Delaware law, may prevent a change in control or management that security holders may consider desirable***

Section 203 of the General Corporation Law of the State of Delaware and our certificate of incorporation and by-laws contain provisions that might enable our management to resist a takeover of our company or discourage a third party from attempting to take over our company. These provisions include the inability of

stockholders to act by written consent or to call special meetings, a classified board of directors and the ability of our board of directors to designate the terms of and issue new series of preferred stock without stockholder approval.

These provisions could have the effect of delaying, deferring, or preventing a change in control of us or a change in our management that stockholders may consider favorable or beneficial. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock or our other securities.

**Item 1B. *Unresolved Staff Comments***

None.

**Item 2. *Properties***

In January 2009, we moved our principal offices to a new office building in Parsippany, New Jersey. The lease covering the new office building covers 173,146 square feet and expires January 2024. In connection with the move, we vacated our previous office space in Parsippany. The lease for our old office facility expires January 2013. In the second half of 2009, we sublet our old office space to two companies. The first sublease, for the second floor of our old office space, expires in March 2011, subject to renewal by the subtenant for up to three periods of six months each and thereafter for one period of four months, and the second sublease, covering the first floor of our previous office space, expires in January 2013.

We also lease small offices and other facilities in Waltham, Massachusetts, U.S.; Milton Park, Abingdon, United Kingdom; Zurich, Switzerland; Paris, France; Rome, Italy; Munich, Germany; Leipzig, Germany; and Montreal, Canada.

We believe our current arrangements will be sufficient to meet our needs for the foreseeable future and that any required additional space will be available on commercially reasonable terms to meet space requirements if they arise.

**Item 3. *Legal Proceedings***

From time to time we are party to legal proceedings in the course of our business in addition to those described below. We do not, however, expect such other legal proceedings to have a material adverse effect on our business, financial condition or results of operations.

*Teva Parenteral Medicines, Inc.*

In September 2009, we were notified that Teva Parenteral Medicines, Inc. had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 patent. The '727 patent was issued on September 1, 2009 and relates to a more consistent and improved Angiomax drug product. The '727 patent expires on July 27, 2028. On October 8, 2009, we filed suit against Teva Parenteral Medicines, Inc., Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd., which we refer to collectively as Teva, in the U.S. District Court for the District of Delaware for infringement of the '727 patent. On October 29, 2009, Teva filed an answer denying infringement and alleging affirmative defenses of non-infringement and invalidity. On October 21, 2009, the case was reassigned in lieu of a vacant judgeship to the U.S. District Court for the Eastern District of Pennsylvania. The court has yet to set a schedule in the case.

On October 08, 2009, we were issued the '343 patent, which relates to a more consistent and improved Angiomax drug product made by processes described in the patent. On January 4, 2010, we filed suit against Teva Parenteral Medicines, Inc. and its related parent entities in the U.S. District Court for the District of Delaware for infringement of the '343 patent. The case was assigned to the same judge in the Eastern District of Pennsylvania as the '727 case above.

*Pliva Hrvatska d.o.o.*

In September 2009, we were notified that Pliva Hrvatska d.o.o. had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 patent. On October 8, 2009, we filed suit against Pliva Hrvatska d.o.o., Pliva d.d., Barr Laboratories, Inc., Barr Pharmaceuticals, Inc., Barr Pharmaceuticals, LLC, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd., which we refer to collectively as Pliva, in the U.S. District Court for the District of Delaware for infringement of the '727 patent. On October 28, 2009, Pliva filed an answer denying infringement and alleging affirmative defenses of non-infringement and invalidity. On October 21, 2009, the case was reassigned in lieu of a vacant judgeship to the U.S. District Court for the Eastern District of Pennsylvania. The court has yet to set a schedule in the case.

On October 08, 2009, we were issued the '343 patent, which relates to a more consistent and improved Angiomax drug product made by processes described in the patent. On January 4, 2010, we filed suit against Pliva Hrvatska d.o.o. and its related parent entities in the U.S. District Court for the District of Delaware for infringement of the '343 patent. The case was assigned to the same judge in the Eastern District of Pennsylvania as the '727 case above.

*APP Pharmaceuticals, LLC*

In September 2009, we were notified that APP Pharmaceuticals, LLC had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 patent. On October 8, 2009, we filed suit against APP Pharmaceuticals, LLC and APP Pharmaceuticals, Inc., which we refer to collectively as APP, in the U.S. District Court for the District of Delaware for infringement of the '727 patent. APP requested and a Stipulation has been filed extending APP's time to answer until December 9, 2009. On October 21, 2009, the case was reassigned in lieu of a vacant judgeship to the U.S. District Court for the Eastern District of Pennsylvania. The court has yet to set a schedule in the case. An amended complaint was filed on February 5, 2010. APP's answer denied infringement and raised counterclaims of invalidity, non-infringement and a request to delist the '727 patent from the Orange Book. On March 1, 2010 we filed a reply denying the counterclaims raised by APP. The court has yet to set a schedule in the case.

*PTO, FDA and U.S. Department of Health and Human Services, et al.*

On January 27, 2010, we filed a complaint in the U.S. District Court for the Eastern District of Virginia against the PTO, the FDA, the U.S. Department of Health and Human Services, et al. seeking to set aside the denial of our application pursuant to the Hatch-Waxman Act to extend the term of the '404 patent. In our complaint, we primarily allege that the PTO and FDA each misinterpreted the filing deadlines in the Hatch-Waxman Act when they rendered their respective determinations that our application for extension of the term of the '404 patent was not timely filed. As a result, we are asking the court to grant relief including to vacate and set aside the PTO's and FDA's determinations regarding the timeliness of our application for patent term extension and to order the PTO to extend the term of the '404 patent for the full period required under the Hatch-Waxman Act. On March 10, 2010, the court conducted a hearing on the parties' cross motions for summary judgment.

**Item 4. (Removed and Reserved)**

**PART II**

**Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

**Market Information and Holders**

Our common stock trades on the NASDAQ Global Select Market under the symbol "MDCO". The following table reflects the range of the high and low sale price per share of our common stock, as reported



on the NASDAQ Global Select Market for the periods indicated. These prices reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

	<b>Common Stock Price</b>	
	<u>High</u>	<u>Low</u>
<b>Year Ended December 31, 2008</b>		
First Quarter . . . . .	\$21.41	\$16.38
Second Quarter . . . . .	21.13	17.18
Third Quarter . . . . .	28.00	19.07
Fourth Quarter . . . . .	24.18	11.37
<b>Year Ended December 31, 2009</b>		
First Quarter . . . . .	\$16.77	\$ 8.73
Second Quarter . . . . .	11.50	6.15
Third Quarter . . . . .	12.12	7.36
Fourth Quarter . . . . .	11.24	7.00

American Stock Transfer & Trust Company is the transfer agent and registrar for our common stock. As of the close of business on March 10, 2010, we had 474 holders of record of our common stock.

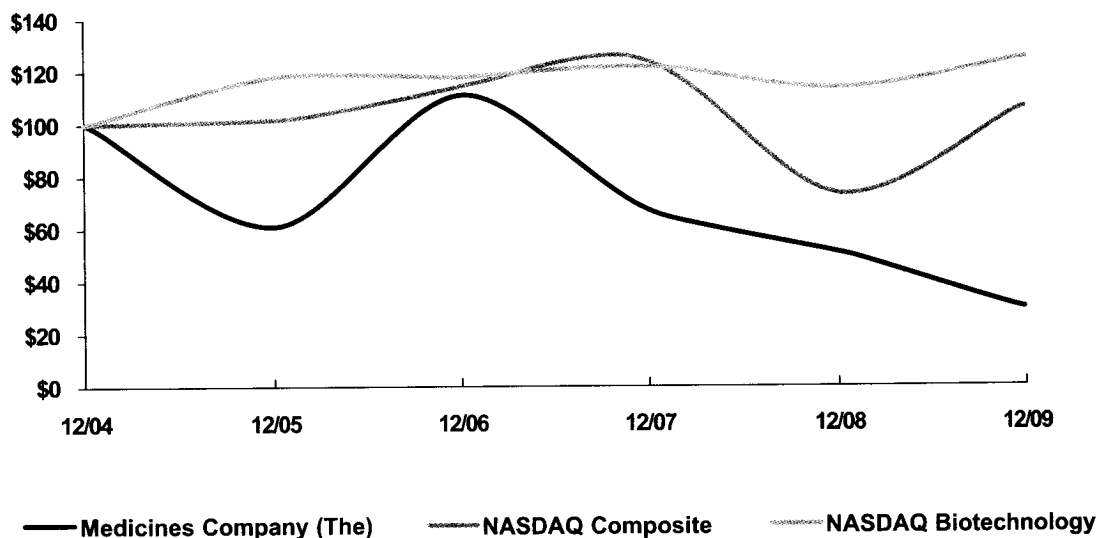
**Dividends**

We have never declared or paid cash dividends on our common stock. We anticipate that we will retain all of our future earnings, if any, for use in the expansion and operation of our business and do not anticipate paying cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors.

## Performance Graph

The graph below matches our cumulative 5-year total return on common equity with the cumulative total returns of the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph tracks the performance of a \$100 investment in our common stock and in each of the indexes (with the reinvestment of all dividends) from December 31, 2004 to December 31, 2009. The stock price performance included in this graph is not necessarily indicative of future stock price performance.

**COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\***  
Among Medicines Company (The), NASDAQ Composite Index  
And The NASDAQ Biotechnology Index



\* Fiscal year ended December 31.

	12/04	12/05	12/06	12/07	12/08	12/09
The Medicines Company . . . . .	100.00	60.59	110.14	66.53	51.15	28.96
NASDAQ Composite . . . . .	100.00	101.33	114.01	123.71	73.11	105.61
NASDAQ Biotechnology . . . . .	100.00	117.54	117.37	121.37	113.41	124.58

This performance graph shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or incorporated by reference into any of our filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, except as shall be expressly set forth by specific reference in such filing.

## Item 6. Selected Financial Data

In the table below, we provide you with our selected consolidated financial data. We have prepared this information using our audited consolidated financial statements for the years ended December 31, 2009, 2008, 2007, 2006 and 2005. In 2006, we computed diluted earnings per share by giving effect to options, restricted stock awards and warrants outstanding at December 31, 2006. We have not included options, restricted stock awards or warrants in the computation of diluted net loss per share for any other periods, as their effects in those periods would have been anti-dilutive. For further discussion of the computation of basic and diluted earnings (loss) per share, please see note 12 of the notes to our consolidated financial statements included in this report.

You should read the following selected consolidated financial data in conjunction with our consolidated financial statements and related notes included in this report and “Item 7 — Management’s Discussion and Analysis of Financial Condition and Results of Operations” of this report.

	Year Ended December 31,				
	2009	2008	2007	2006	2005
	(In thousands, except per share data)				
<b>Statements of Operations Data</b>					
Net revenue . . . . .	\$404,241	\$348,157	\$257,534	\$213,952	\$150,207
Operating expenses:					
Cost of revenue . . . . .	118,148	88,355	66,502	51,812	34,762
Research and development . . . . .	117,610	105,720	77,255	63,536	64,389
Selling, general and administrative . . . . .	193,832	164,903	141,807	88,265	63,053
Total operating expenses . . . . .	429,590	358,978	285,564	203,613	162,204
(Loss) income from operations . . . . .	(25,349)	(10,821)	(28,030)	10,339	(11,997)
Other (expense) income . . . . .	(2,818)	5,235	10,653	7,319	4,344
(Loss) income before income taxes . . . . .	(28,167)	(5,586)	(17,377)	17,658	(7,653)
(Provision for) benefit from income taxes . . . . .	(48,062)	(2,918)	(895)	46,068	(100)
Net (loss) income . . . . .	\$ (76,229)	\$ (8,504)	\$ (18,272)	\$ 63,726	\$ (7,753)
Basic (loss) earnings per common share . . . . .	\$ (1.46)	\$ (0.16)	\$ (0.35)	\$ 1.27	\$ (0.16)
Diluted (loss) earnings per common share . . . . .	\$ (1.46)	\$ (0.16)	\$ (0.35)	\$ 1.25	\$ (0.16)
Shares used in computing basic (loss) earnings per common share . . . . .	52,269	51,904	51,624	50,300	49,443
Shares used in computing diluted (loss) earnings per common share . . . . .	52,269	51,904	51,624	51,034	49,443
	As of December 31,				
	2009	2008	2007	2006	2005
	(In thousands)				
<b>Balance Sheet Data</b>					
Cash and cash equivalents, available for sale securities and accrued interest receivable . . . . .	\$ 177,113	\$ 217,542	\$ 223,711	\$ 198,231	\$ 141,012
Working capital . . . . .	156,103	212,222	208,568	228,523	169,912
Total assets . . . . .	374,776	387,404	361,516	318,568	208,707
Accumulated deficit . . . . .	(344,177)	(267,948)	(259,444)	(241,172)	(304,898)
Total stockholders’ equity . . . . .	240,389	298,025	277,896	269,951	170,899

Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS 123(R), “Share-Based Payment”, which was later superseded by the FASB Codification and included in ASC topic 718-10, or ASC 718-10, using the accelerated expense attribution method. ASC 718-10 requires us to recognize compensation expense in an amount equal to the fair value of all share-based awards granted to employees, resulting in \$19.4 million, \$22.8 million, \$15.4 million and \$8.5 million in share-based compensation expense during 2009, 2008, 2007 and 2006, respectively.

## **Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*You should read the following discussion and analysis of our financial condition and results of operations together with "Selected Consolidated Financial Data" and our financial statements and accompanying notes included elsewhere in this annual report. In addition to the historical information, the discussion in this annual report contains certain forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated by the forward-looking statements due to our critical accounting estimates discussed below and important factors set forth in this annual report, including under "Risk Factors" in Item 1A of this annual report.*

### **Overview**

#### ***Our Business***

We are a global pharmaceutical company focused on advancing the treatment of critical care patients through the delivery of innovative, cost-effective medicines to the worldwide hospital marketplace. We have two marketed products, Angiomax<sup>®</sup> (bivalirudin) and Cleviprex<sup>®</sup> (clevidipine butyrate) injectable emulsion, and a pipeline of critical care hospital products in development, including two late-stage development product candidates, cangrelor and oritavancin, two early stage development product candidates, CU2010 and ApoA-I Milano, and marketing rights in the United States and Canada to a ready-to-use formulation of Argatroban for which a new drug application, or NDA, has been submitted to the U.S. Food and Drug Administration, or FDA. We believe that Angiomax, Cleviprex and our products in development possess favorable attributes that competitive products do not provide, can satisfy unmet medical needs in the critical care hospital product market and offer, or, in the case of our products in development, have the potential to offer, improved performance to hospital businesses.

We market and sell Angiomax and Cleviprex in the United States with a sales force that, as of February 15, 2010, consisted of 132 representatives and managers experienced in selling to hospital customers. In Europe, we market and sell Angiox with a sales force that, as of February 15, 2010, consisted of 51 representatives and managers experienced in selling to hospital customers. Our revenues to date have been generated primarily from sales of Angiomax in the United States, but we continue to expand our sales and marketing efforts in Europe. We believe that by establishing operations in Europe for Angiox, we will be positioned to commercialize our pipeline of critical care product candidates in Europe, if and when they are approved.

Research and development expenses represent costs incurred for company acquisitions and license of rights to products, clinical trials, nonclinical and preclinical studies, activities relating to regulatory filings and manufacturing development efforts. We outsource much of our clinical trials, nonclinical and preclinical studies and all of our manufacturing development activities to third parties to maximize efficiency and minimize our internal overhead. We expense our research and development costs as they are incurred. Selling, general and administrative expenses consist primarily of salaries and related expenses, general corporate activities and costs associated with marketing and promotional activities. Research and development expense, selling, general and administrative expense and cost of revenue also include stock-based compensation expense, which we allocate based on the responsibilities of the recipients of the stock-based compensation.

Except for 2004 and 2006, we have incurred net losses on an annual basis since our inception. As of December 31, 2009, we had an accumulated deficit of approximately \$344.2 million. We expect to make substantial expenditures to further develop and commercialize our products, including costs and expenses associated with clinical trials, nonclinical and preclinical studies, regulatory approvals and commercialization. Although we achieved profitability in 2004 and in 2006, we have not been profitable on an annual basis since 2006. We will likely need to generate significantly greater revenue in future periods to achieve and maintain profitability in light of our planned expenditures.

### ***Angiomax Patent Term***

The principal U.S. patent covering Angiomax expires on March 23, 2010. We will then have a six-month period of market exclusivity for Angiomax in the United States which will expire on September 23, 2010 due to our study of Angiomax in the pediatric setting. We applied, under the Hatch-Waxman Act, for an extension of the term of the principal patent. However, the United States Patent Trademark Office, or PTO, rejected our application because in its view the application was not timely filed. We have filed suit against the PTO, the FDA and the U.S. Department of Health and Human Services seeking to set aside the denial of our application to extend the term of the principal patent. We have also sought legislative action to address the matter. In addition, the PTO recently issued two patents to us covering a more consistent and improved Angiomax drug product and the processes by which it is made. In October 2009 and January 2010, we filed suit against pharmaceutical companies which have filed abbreviated new drug applications, or ANDAs, with the FDA for generic versions of Angiomax, alleging infringement of the two recently issued patents. If we are unsuccessful in extending the term of the principal patent and depending on the protection afforded by our two new patents, Angiomax could be subject to generic competition in the United States as early as September 23, 2010. In Europe, the principal patent covering Angiox expires in 2015.

### ***Distribution and Sales***

We distribute Angiomax and Cleviprex in the United States through a sole source distribution model. Under this model, we sell Angiomax and Cleviprex to our sole source distributor, Integrated Commercialization Solutions, Inc., or ICS, which then sells Angiomax and Cleviprex to a limited number of national medical and pharmaceutical wholesalers with distribution centers located throughout the United States and in certain cases, directly to hospitals. Our agreement with ICS, which we initially entered into February 2007, provides that ICS will be our exclusive distributor of Angiomax and Cleviprex in the United States. Under the terms of this fee-for-service agreement, ICS assumes all credit and inventory risks, is subject to our standard return policy, places orders with us for sufficient quantities of Angiomax and Cleviprex to maintain an appropriate level of inventory based on our customers' historical purchase volumes and has sole responsibility for determining the prices at which it sells Angiomax and Cleviprex, subject to specified limitations in the agreement. The agreement terminates on February 28, 2011, but will automatically renew for additional one-year periods unless either party gives notice at least 120 days prior to the automatic extension. We may also terminate the agreement at any time and for any reason upon prior written notice to ICS and payment of a termination fee of between \$100,000 and \$250,000.

In Europe, we market and sell Angiox with a sales force that, as of February 15, 2010, consisted of 51 representatives and managers. We also market and sell Angiomax outside the United States through distributors, including Sepracor Inc., which distributes Angiomax in Canada, and affiliates of Grupo Ferrer Internacional, which distribute Angiox in Greece, Portugal and Spain and in a number of countries in Central America and South America. We also have agreements with other third parties for other countries outside of the United States and Europe, including Israel and Australia. We are developing a global strategy for Cleviprex in preparation for its potential approval outside of the United States.

The reacquisition of all development, commercial and distribution rights for Angiox from Nycomed Danmark ApS, or Nycomed, in 2007 was our first step directly into international markets. In July 2007, we entered into a series of agreements with Nycomed pursuant to which we terminated our prior distribution agreement with Nycomed and re-acquired all development, commercial and distribution rights for Angiox in the European Union (excluding Spain, Portugal and Greece) and the former Soviet republics, which we refer to as the Nycomed territory. Prior to entering into the 2007 Nycomed agreements, Nycomed served as the exclusive distributor of Angiox in the Nycomed territory pursuant to a sales, marketing and distribution agreement, dated March 25, 2002, as amended. Pursuant to the 2007 Nycomed agreements, we and Nycomed agreed to transition the Angiox rights held by Nycomed to us. Under these arrangements, including a transitional distribution agreement, we assumed control of the marketing of Angiox immediately and Nycomed provided, on a transitional basis, sales operations services, until December 31, 2007 and product distribution services until the second half of 2008. We assumed control of the distribution of Angiox in the Nycomed territory during the second half of 2008.

Under the terms of the transitional distribution agreement with Nycomed, upon the sale by Nycomed to third parties of vials of Angiox purchased by Nycomed from us prior to July 1, 2007, which we refer to as existing inventory, Nycomed agreed to pay us a specified percentage of Nycomed's net sales of Angiox, less the amount previously paid by Nycomed to us for the existing inventory. Under the transitional distribution agreement, upon the termination of the agreement, Nycomed had the right to return any existing inventory for the price paid by Nycomed to us for such inventory. We recorded a reserve of \$3.0 million in the fourth quarter of 2007 for the existing inventory at Nycomed which we did not believe would be sold prior to the termination of the transitional distribution agreement and would be subject to return by Nycomed in accordance with the agreement. During 2008, we reduced the reserve by \$2.2 million as Nycomed sold a portion of its existing inventory during the year. Accordingly, we included within our accrual for product return at December 31, 2008 a reserve of \$0.8 million for existing inventory at Nycomed that Nycomed had the right to return at any time. In July 2009, we reimbursed Nycomed \$0.8 million for the final amount of inventory held by Nycomed at December 31, 2008. The transitional distribution agreement terminated on December 31, 2008.

We incurred total costs of \$45.7 million in connection with the reacquisition of the rights to develop, distribute and market Angiox in the Nycomed territory. These total costs include transaction fees of approximately \$0.7 million and agreed upon milestone payments of \$20.0 million paid to Nycomed on July 2, 2007, \$15.0 million paid to Nycomed on January 15, 2008 and \$5.0 million paid to Nycomed on July 8, 2008, as well as an additional \$5.0 million paid to Nycomed on July 8, 2008 in connection with our obtaining European Commission approval to market Angiox for ACS in January 2008.

During the third quarter of 2007, we allocated \$30.8 million of these costs as expense attributable to the termination of the prior distribution agreement with Nycomed and \$14.9 million to intangible assets. The \$30.8 million expense was offset in part by the write-off of approximately \$2.7 million of deferred revenue, which amount represented the unamortized portion of deferred revenue related to milestone payments received from Nycomed in 2004 and 2002. We included such amounts in selling, general and administrative expense on the consolidated statements of operations for the year ended December 31, 2007. We allocated approximately \$14.9 million of the costs associated with the reacquisition of the rights to develop, distribute and market Angiox in the European Union to intangible assets. We are amortizing these intangible assets over the remaining patent life of Angiox, which expires in 2015. The period in which amortization expense will be recorded reflects the pattern in which we expect the economic benefits of the intangible assets to be consumed.

To support the marketing, sales and distribution efforts of Angiomax, we are continuing to develop our business infrastructure outside the United States. We initiated research to understand the PCI market, as well as the hypertension market, on a global basis, including profiling hospitals and identifying key opinion leaders. Since reacquiring the development, commercial and distribution rights for Angiox from Nycomed, we have formed subsidiaries in the Netherlands, Switzerland, Germany, France, Italy, Sweden, Poland, Denmark, Austria, Belgium, Finland, Norway and Spain, in addition to our pre-existing subsidiary in the United Kingdom, in connection with the development of a business infrastructure to conduct the international sales and marketing of Angiox. We also obtained licenses and authorizations necessary to distribute Angiox in the various countries in Europe, hired new personnel and entered into third-party arrangements to provide services, such as importation, packaging, quality control and distribution. We believe that by establishing operations in Europe for Angiox, we will be positioned to commercialize our products in development, if and when they are approved.

### ***Business Development Activity***

Our core strategy is to acquire, develop and commercialize products that we believe help hospitals treat patients more efficiently by improving the effectiveness and safety of treatment while reducing cost. Since 2007, we have acquired or licensed a portfolio of critical care products that we are developing.

***Curacyte Discovery Acquisition.*** In August 2008, we acquired Curacyte Discovery GmbH, or Curacyte Discovery, a wholly owned subsidiary of Curacyte AG. Curacyte Discovery, a German limited liability

company, was primarily engaged in the discovery and development of small molecule serine protease inhibitors. Its lead compound, CU2010, is being developed for the prevention of blood loss during surgery. In connection with the acquisition, we paid Curacyte AG an initial payment of €14.5 million (approximately \$22.9 million at the time of payment) and €3.5 million in December 2009 and agreed to pay contingent milestone payments of up to €32.0 million if we proceed with further clinical development of CU2010 and achieve a commercial milestone. In addition, we agreed to pay royalties based on net sales.

The total cost of the Curacyte acquisition was approximately \$23.7 million, which consisted of a purchase price of approximately \$22.9 million and direct acquisition costs of \$0.8 million. Since the acquisition date, we have included results of Curacyte Discovery's operations in our consolidated financial statements. We allocated the purchase price to the estimated fair value of assets acquired and liabilities assumed based on a third-party valuation and management estimates. We allocated approximately \$21.4 million of the purchase price to in-process research and development, which we expensed upon completion of the acquisition. We recorded this amount as research and development expenses in our consolidated statements of operations for the three months ended September 30, 2008. We allocated the remaining portion of the purchase price to net tangible assets.

*Targanta Acquisition.* In February 2009, we acquired Targanta, a biopharmaceutical company focused on developing and commercializing innovative antibiotics to treat serious infections in the hospital and other institutional settings. Targanta's product pipeline included an intravenous version of oritavancin and a program to develop an oral version of oritavancin for the possible treatment of *Clostridium difficile* infections, or *C. difficile*.

Under the terms of our agreement with Targanta, we paid Targanta shareholders an aggregate of approximately \$42.0 million at closing, and agreed to pay contingent cash payments up to an additional \$90.4 million in the aggregate, as described below:

- Upon approval from the EMEA for a MAA for oritavancin for the treatment of ABSSSI on or before December 31, 2013, approximately \$15.8 million if such approval is granted between January 1, 2010 and June 30, 2010, or approximately \$10.5 million if such approval is granted between July 1, 2010 and December 31, 2013. As of March 1, 2010, we have not filed an application with the EMEA for oritavancin for the treatment of ABSSSI.
- Upon final approval from the FDA for a new drug application, or NDA, for oritavancin for the treatment of ABSSSI (1) within 40 months after the date the first patient is enrolled in a Phase 3 clinical trial of ABSSSI that is initiated by us and (2) on or before December 31, 2013, approximately \$10.5 million in the aggregate.
- Upon final FDA approval for an NDA for the use of oritavancin for the treatment of ABSSSI administered by a single dose intravenous infusion (1) within 40 months after the date the first patient is enrolled in a Phase 3 clinical trial of ABSSSI that is initiated by us and (2) on or before December 31, 2013, approximately \$14.7 million in the aggregate. This payment may become payable simultaneously with the payment described in the previous bullet above.
- If aggregate net sales of oritavancin in four consecutive calendar quarters ending on or before December 31, 2021 reach or exceed \$400 million, approximately \$49.4 million in the aggregate.

The transaction costs were expensed as incurred, the value of acquired in-process research and development was capitalized as an indefinite lived intangible asset and contingent payments were recorded at their estimated fair value. The results of Targanta's operations since the acquisition date have been included in our consolidated financial statements. The purchase price of approximately \$64 million, which includes \$42 million of cash paid upon acquisition and \$23 million that represents the fair market value of the contingent purchase price on the date of acquisition, was allocated to the net tangible and intangible assets of Targanta based on their estimated fair values.

As a result of our acquisition of Targanta, we are a party to an asset purchase agreement that Targanta entered into with InterMune, Inc., or InterMune, in connection with Targanta's December 2005 acquisition of

the worldwide rights to oritavancin from InterMune. Under the agreement, we are obligated to use commercially reasonable efforts to develop oritavancin and to make a \$5.0 million cash payment to InterMune if and when we receive from the FDA all approvals necessary for the commercial launch of oritavancin. We have no other milestone or royalty obligations to InterMune.

*Licensing Arrangement with Eagle.* In September 2009, we licensed marketing rights in the United States and Canada to a ready-to-use formulation of Argatroban developed by Eagle Pharmaceuticals, Inc., or Eagle, for which Eagle has submitted an NDA. Under the license agreement with Eagle, we paid Eagle a \$5.0 million technology license fee. We also agreed to pay additional approval and commercialization milestones up to a total of \$15.0 million and royalties. Eagle has agreed to supply us with the ready-to-use product under a supply agreement we entered into with it in September 2009.

*Licensing Arrangement with Pfizer.* In December 2009, we licensed exclusive worldwide rights to ApoA-1 Milano from Pfizer. Under the terms of the agreement, we paid Pfizer an up-front payment of \$10.0 million and agreed to make additional payments upon the achievement of clinical, regulatory and sales milestones up to a total of \$410 million. We also agreed to pay Pfizer single-digit royalty payments on worldwide net sales of ApoA-1 Milano. We also paid \$7.5 million to third parties in connection with the license and agreed to make additional payments to them of up to \$12.0 million in the aggregate upon the achievement of specified development milestones and continuing payments based on sales of ApoA-I Milano.

### ***Cleviprex Recall***

On December 16, 2009, we conducted a voluntary recall of 11 lots of Cleviprex due to the presence of visible particulate matter that was deposited at the bottom of some vials and was observed in such vials during a routine annual inspection. We are scheduled to extend our voluntary recall in March 2010 to include four additional manufactured lots of Cleviprex that now also show visible particulate matter that was deposited at the bottom of some vials. As a result, we are not able to supply the market at this time with existing inventory or using the current manufacturing method. We are cooperating with the FDA and our contract manufacturer on these recalls and to remedy the problem at the manufacturing site. If the manufacturing problem is remedied, we anticipate being able to supply the market in the second quarter of 2010. If the problem is not remedied, we may pursue production of drug product using other approaches, which could delay the supply of Cleviprex up to 18 months.

### ***Workforce Reductions***

On January 7, 2010 and February 9, 2010, we commenced two separate workforce reductions to improve efficiencies and better align our costs and structure for the future. As a result of the first workforce reduction, we reduced our office-based personnel by 30 employees. The second workforce reduction resulted in a reduction of 42 primarily field-based employees. We expect to record, in the aggregate, charges of approximately \$7.0 million associated with these workforce reductions, which will be recognized in the first quarter of 2010. Substantially all of these charges are expected to represent cash expenditures. We expect to realize estimated annualized cost savings from the workforce reductions in the range of \$14.5 to \$16.5 million starting in the first quarter of 2010.



## Results of Operations

### Years Ended December 31, 2009 and 2008

#### Net Revenue:

Net revenue increased 16% to \$404.2 million for 2009 as compared to \$348.2 million for 2008. The following table reflects the components of net revenue for the years ended December 31, 2009 and 2008:

	Net Revenue		Change \$	Change %
	Year Ended December 31, 2009	Year Ended December 31, 2008		
	(In thousands)			
<b>Net Revenue</b>				
U.S. sales . . . . .	\$385,939	\$334,582	\$51,357	15.3%
International net revenue . . . . .	18,302	9,750	8,552	87.7%
<i>Revenue from collaborations, net</i> . . . . .	—	3,825	(3,825)	(100)%
<b>Total net revenue</b> . . . . .	<u>\$404,241</u>	<u>\$348,157</u>	<u>\$56,084</u>	<u>16.1%</u>

Net sales during 2009 increased \$56.1 million compared to 2008 primarily due to an increase in sales of Angiomax in the United States and an increase in European sales of Angiox. This increase was a result of increased demand by existing hospital customers, the addition of new hospital customers and a price increase we implemented in May 2009. Of the approximate 14.6% increase in U.S. sales of Angiomax in 2009 compared to 2008, approximately 10.9% was related to increased hospital demand by existing customers and the addition of new customers and 3.7% was attributable to the price increase in May 2009. U.S. sales also include net revenue of \$3.0 million in 2009 compared to \$0.4 million in 2008 from sales of Cleviprex. The \$3.0 million in sales of Cleviprex in 2009 includes an offset of \$1.3 million due to a returns reserve related to a voluntary recall we conducted in December 2009 of 11 lots of Cleviprex due to the presence of visible particulate matter that was observed in some vials during a routine annual inspection.

International net revenue increased by \$8.6 million during 2009 compared to 2008 primarily as a result of direct sales we made after assuming control of the distribution in the European Union of Angiox in 2008, as well as increased orders from our international distributors. We assumed control of the distribution of Angiox in the majority of the countries in the Nycomed territory during the third quarter of 2008 and the remainder in the fourth quarter of 2008.

During 2008, we recognized as revenue from collaborations approximately \$3.8 million of net revenue from 2008 Angiox sales of approximately \$8.2 million made by Nycomed under our transitional distribution agreement with Nycomed which terminated on December 31, 2008. Under the terms of this transitional distribution agreement, upon the sale by Nycomed to third parties of vials of Angiox, Nycomed paid us a specified percentage of Nycomed's net sales of Angiox, less the amount previously paid by Nycomed to us for the existing inventory. In July 2009, we reimbursed Nycomed \$0.8 million for the final amount of inventory held by Nycomed at December 31, 2008.

If we are unable to extend the patent term of the principal U.S. patent covering Angiomax beyond March 23, 2010 or to maintain our market exclusivity for Angiomax in the United States through enforcement of our other U.S. patents covering Angiomax, Angiomax could be subject to generic competition as early as September 23, 2010. Competition from generic equivalents sold at a price that is less than the price at which we currently sell Angiomax could reduce our revenues, possibly materially.

If the manufacturing problem related to Cleviprex that resulted in our recall and scheduled recall of Cleviprex is remedied, we anticipate being able to supply the market with drug product in the second quarter of 2010. If the problem is not remedied, we may pursue production of drug product using other approaches, which could delay the supply of Cleviprex up to 18 months.

*Cost of Revenue:*

Cost of revenue in 2009 was \$118.1 million, or 29% of net revenue, compared to \$88.4 million, or 25% of net revenue, in 2008. Cost of revenue consisted of expenses in connection with the manufacture of Angiomax and Cleviprex sold, royalty expenses under our agreements with Biogen Idec and Health Research Inc. related to Angiomax and with AstraZeneca AB, or AstraZeneca, related to Cleviprex and the logistics costs of selling Angiomax and Cleviprex, such as distribution, storage, and handling.

**Cost of Revenue**

<u>Cost of Revenue</u>	<u>Year Ended December 31,</u>			
	<u>2009</u>	<u>% of Total</u>	<u>2008</u>	<u>% of Total</u>
	<u>(In thousands)</u>	<u>Cost</u>	<u>(In thousands)</u>	<u>Cost</u>
Manufacturing .....	\$ 28,520	24%	\$22,518	25%
Royalty .....	77,786	66%	53,642	61%
Logistics .....	11,842	10%	12,195	14%
<b>Total cost of revenue .....</b>	<b><u>\$118,148</u></b>	<b><u>100%</u></b>	<b><u>\$88,355</u></b>	<b><u>100%</u></b>

Cost of revenue increased \$29.8 million during 2009 compared to 2008. Approximately \$24.1 million of the total cost of revenue increase related to an increase in royalty expense due to a higher effective royalty rate to Biogen Idec, \$3.3 million related to an increase in manufacturing costs of Angiomax due to production failures at the third-party manufacturer for Angiomax and increased logistic costs and \$2.3 million related to inventory write offs associated with the Cleviprex recall.

*Research and Development Expenses:*

Research and development expenses increased by 11% to \$117.6 million for 2009, compared to \$105.7 million for 2008. The increase primarily reflects licensing fees paid in connection with the licensing of rights to ApoA-I Milano and the ready-to-use formulation of Argatroban, the acquisition of Targanta and Angiomax lifecycle management activities, offset by a decrease in acquired in process research and development expenses related to our acquisition of Curacyte Discovery in 2008 and a decrease in cangrelor phase 3 clinical trial costs as a result of our discontinuation of enrollment in the CHAMPION trials.

We expect to continue to invest in the development of Angiomax, Cleviprex, cangrelor, oritavancin, CU2010 and ApoA-I Milano during 2010. We expect research and development expenses to reflect costs associated with our anticipated Phase 3 clinical trials of oritavancin and cangrelor, Phase 4 trials of Cleviprex, manufacturing development activities for Cleviprex and cangrelor, our Phase 1 clinical trial program for CU2010 and product lifecycle management activities.

The following table identifies for each of our major research and development projects, our spending for 2009 and 2008. Spending for past periods is not necessarily indicative of spending in future periods.

### Research and Development Spending

<u>Research and Development</u>	<u>Year Ended December 31,</u>			
	<u>2009</u>	<u>% of</u>	<u>2008</u>	<u>% of</u>
	<u>(In thousands)</u>	<u>Total R&amp;D</u>	<u>(In thousands)</u>	<u>Total R&amp;D</u>
<b>Angiomax</b>				
Clinical trials . . . . .	\$ 5,335	4%	\$ 4,959	5%
Manufacturing development . . . . .	12,467	11%	3,924	4%
Administrative and headcount costs . . . . .	4,437	4%	3,711	3%
<b>Total Angiomax</b> . . . . .	<u>22,239</u>	<u>19%</u>	<u>12,594</u>	<u>12%</u>
<b>Cleviprex</b>				
Clinical trials . . . . .	4,758	4%	3,031	3%
Manufacturing development . . . . .	1,443	1%	2,484	2%
Administrative and headcount costs . . . . .	5,025	4%	6,214	6%
<b>Total Cleviprex</b> . . . . .	<u>11,226</u>	<u>9%</u>	<u>11,729</u>	<u>11%</u>
<b>Cangrelor</b>				
Clinical trials . . . . .	21,680	19%	37,090	35%
Manufacturing development . . . . .	2,665	2%	2,661	3%
Administrative and headcount costs . . . . .	4,640	4%	4,658	4%
<b>Total Cangrelor</b> . . . . .	<u>28,985</u>	<u>25%</u>	<u>44,409</u>	<u>42%</u>
<b>Oritavancin</b>				
Clinical trials . . . . .	4,593	4%	—	0%
Manufacturing development . . . . .	3,587	3%	—	0%
Administrative and headcount costs . . . . .	3,086	3%	—	0%
<b>Total Oritavancin</b> . . . . .	<u>11,266</u>	<u>10%</u>	<u>—</u>	<u>0%</u>
<b>CU2010</b>				
Clinical trials . . . . .	2,129	2%	—	0%
Manufacturing development . . . . .	1,042	1%	—	0%
Administrative and headcount costs . . . . .	2,717	2%	1,180	1%
Acquisition related in-process research and development . . . . .	—	0%	21,373	20%
Clinical milestone . . . . .	5,182	4%	—	0%
Government subsidy . . . . .	(1,432)	(1)%	—	0%
<b>Total CU2010</b> . . . . .	<u>9,638</u>	<u>8%</u>	<u>22,553</u>	<u>21%</u>
<b>ApoA-I Milano</b>				
Acquisition license fee . . . . .	17,500	15%	—	0%
<b>Total ApoA-I Milano</b> . . . . .	<u>17,500</u>	<u>15%</u>	<u>—</u>	<u>0%</u>
<b>Ready-to-Use Argatroban</b>				
Acquisition license fee . . . . .	5,000	4%	—	0%
<b>Total Ready-to-Use Argatroban</b> . . . . .	<u>5,000</u>	<u>4%</u>	<u>—</u>	<u>0%</u>
<b>Other</b> . . . . .	<u>11,756</u>	<u>10%</u>	<u>14,435</u>	<u>14%</u>
<b>Total</b> . . . . .	<u>\$117,610</u>	<u>100%</u>	<u>\$105,720</u>	<u>100%</u>

#### Angiomax

Research and development spending related to Angiomax during 2009 increased by approximately \$9.6 million compared to 2008, primarily due to an increase in manufacturing development expenses related to product lifecycle management activities. Administrative costs increased \$0.7 million primarily in connection with costs incurred in connection with the regulatory filing related to a clinical study report

for the pediatric extension filed with the FDA in the second quarter of 2009. Clinical trial costs increased approximately \$0.4 million primarily due to increased expenditures in connection with our EUROMAX clinical trial, which commenced enrollment on March 12, 2010, which were partially offset by decreased expenditures associated with the investigator initiated trial, HORIZONS AMI, that we supported. During the second quarter of 2008, we incurred \$1.5 million in costs related to the final milestone payment in connection with HORIZONS AMI.

We plan to continue to incur research and development expenses relating to Angiomax in connection with our efforts to further develop Angiomax for use in additional patient populations and our plan to increase our product lifecycle management activities.

#### *Cleviprex*

Research and development expenditures for Cleviprex decreased approximately \$0.5 million during 2009 compared 2008. The decrease in research and development expenditures primarily relates to decreased manufacturing development expenses associated with product lifecycle management activities and a decrease in administrative and headcount costs primarily due to a reduction in administrative activity in 2009 related to our MAA for Cleviprex in the European Union, which we submitted during the first quarter of 2009. These decreases were partially offset by increased clinical trial expenses due to the numerous Phase 4 and other clinical studies of Cleviprex we are conducting in areas such as intracranial hemorrhage, major cardiovascular surgery, neurocritical care and hypertension associated with congestive heart failure, along with health economics analyses.

#### *Cangrelor*

Research and development expenditures related to cangrelor decreased by approximately \$15.4 million in 2009 compared to 2008. In May 2009, we discontinued enrollment in our Phase 3 CHAMPION clinical trial program for cangrelor. Manufacturing development expenses and administrative and headcount costs remained relatively unchanged. Subject to the completion of ongoing discussions with the FDA, leading experts in ischemic heart disease and AstraZeneca, which licensed cangrelor to us, we plan to initiate a new Phase 3 clinical trial of cangrelor in 2010.

#### *Oritavancin*

With our acquisition of Targanta in February 2009, we acquired a worldwide exclusive license to oritavancin. Subject to the completion of ongoing discussions with the FDA, we expect to commence a Phase 3 clinical trial of oritavancin in 2010 for the treatment of ABSSSI. In August 2009, we withdrew the European MAA for oritavancin. Costs incurred during the year ended December 31, 2009 primarily relate to Phase 3 clinical trials, manufacturing costs and headcount. The results of Targanta's operations are included in our consolidated financial statements as of the acquisition date.

#### *CU2010*

We acquired CU2010 in August 2008 in connection with our acquisition of Curacyte Discovery. CU2010 is a small molecule serine protease inhibitor that we are developing for the prevention of blood loss during surgery. The acquisition of Curacyte Discovery resulted in the inclusion in research and development expense of \$21.4 million of acquisition related in-process research and development in 2008. Costs incurred during 2009 primarily relate to a clinical milestone of \$5.2 million that we paid in December 2009, our Phase 1a clinical trial of CU2010, which we commenced in July 2009, and headcount. Such research and develop expense was partially offset by a \$1.4 million German government research and development subsidy. We plan to submit an IND for CU2010 to the FDA in 2010.

#### *ApoA-I Milano*

In December 2009, we paid \$17.5 million in license fees to Pfizer and additional payments to other third parties for exclusive worldwide rights to ApoA-I Milano.

### *Argatroban*

In September 2009, we paid a \$5.0 million technology license fee to Eagle for marketing rights for a ready-to-use formulation of Argatroban in the United States and Canada.

### *Other*

Spending in this category includes infrastructure costs in support of our product development efforts, which includes expenses for data management, statistical analysis, analysis of pre-clinical data, analysis of pharmacokinetic-pharmacodynamic (PK/PD) data and product safety as well as expenses related to business development activities in connection with our efforts to evaluate early stage and late stage compounds for development and commercialization and other strategic opportunities. Spending in this category decreased by approximately \$2.7 million during 2009 compared to 2008, primarily due to a reduction of business development expenses.

Our success in further developing Angiomax, obtaining marketing approvals for Cleviprex outside the United States, and developing and obtaining marketing approval for our products in development, is highly uncertain. We cannot predict expenses associated with ongoing data analysis or regulatory submissions, if any. Nor can we reasonably estimate or know the nature, timing and estimated costs of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from, Cleviprex outside the United States, or our products in development due to the numerous risks and uncertainties associated with developing and commercializing drugs, including the uncertainty of:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- future clinical trial results;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- the cost and timing of establishing and maintaining sales, marketing and distribution capabilities;
- the cost of establishing and maintaining clinical and commercial supplies of our product candidates;
- the effect of competing technological and market developments; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

### *Selling, General and Administrative Expenses:*

	<u>Year Ended December 31,</u>		<u>Change</u>	<u>Change</u>
	<u>2009</u>	<u>2008</u>	<u>\$</u>	<u>%</u>
	<u>(In thousands)</u>			
Selling, general and administrative expenses . . . . .	\$193,832	\$164,903	\$28,929	17.5%

The increase in selling, general and administrative expenses of \$28.9 million includes an increase in expenses of \$12.3 million related to the sales force expansion in the United States in connection with the Cleviprex launch and in Europe in connection with Angiox, \$18.6 million related to business infrastructure, which included \$7.5 million for global facilities expansion and rent, \$2.4 million of information technology related expenses, and \$1.6 million related to the building of our business infrastructure in Europe. In addition, we incurred in 2009 a total of \$10.2 million of cost related to our acquisitions of Targanta and Curacyte Discovery, of which \$4.3 million transaction cost related to Targanta. The increase in selling, general and administrative expenses was partially offset by a \$9.3 million decrease in marketing, promotional and support expense reflecting higher spending in 2008 related to the Cleviprex launch in 2008 and a \$3.4 million decrease in stock-based compensation expense.

*Other (Expense) Income:*

	<b>Year Ended December 31,</b>		<b>Change \$</b>	<b>Change %</b>
	<b>2009</b>	<b>2008</b>		
(In thousands)				
Other (expense) income . . . . .	\$(2,818)	\$5,235	\$(8,053)	(153.8)%

Other (expense) income, which is comprised of interest income and gains and losses on foreign currency transactions and impairment of investment, decreased \$8.1 million to \$2.8 million of expense for 2009, from \$5.2 million of income for 2008. This decrease was primarily due to a \$5.0 million impairment charge taken with respect to our equity investment in Eagle and to lower levels of cash to invest combined with lower rates of return on our available for sale securities in 2009.

*(Provision for) Income Tax:*

	<b>Year Ended December 31,</b>		<b>Change \$</b>	<b>Change %</b>
	<b>2009</b>	<b>2008</b>		
(In thousands)				
(Provision for) income tax . . . . .	\$(48,062)	\$(2,918)	\$(45,144)	(1,547.1)%

We recorded a provision for income taxes of \$48.1 million in 2009 and \$2.9 million in 2008, based on losses before income taxes of \$28.2 million and \$5.6 million, respectively. The increase in the provision for income taxes was driven mainly by our decision to fully reserve against our deferred tax assets as it is more likely than not that we will not realize the future benefit of these assets.

Although we maintain a full valuation allowance against our deferred tax assets, we will continue to evaluate their future realizability on a periodic basis in light of changing facts and circumstances. These would include but are not limited to future projections of taxable income, tax legislation, rulings by relevant tax authorities, the progress of ongoing tax audits, the regulatory approval of products currently under development, extension of the patent rights relating to Angiomax and the ability to achieve future anticipated revenues. If we reduce the valuation allowance on deferred tax assets in future years, we would recognize a tax benefit.

***Years Ended December 31, 2008 and 2007***

*Net Revenue:*

Net revenue increased 35% to \$348.2 million for 2008 as compared to \$257.5 million for 2007. The following table reflects the components of net revenue for the years ended December 31, 2008 and 2007:

	<b>Year Ended December 31,</b>		<b>Change \$</b>	<b>Change %</b>
	<b>2008</b>	<b>2007</b>		
(In thousands)				
<b>Net Revenue</b>				
U.S. sales . . . . .	\$334,582	\$254,975	\$79,607	31.2%
International net revenue . . . . .	9,750	32	9,718	303.7%
<b>Revenue from collaborations, net</b> . . . . .	<u>3,825</u>	<u>2,527</u>	<u>1,298</u>	<u>51.4%</u>
<b>Total net revenue</b> . . . . .	<u>\$348,157</u>	<u>\$257,534</u>	<u>\$90,623</u>	<u>35.2%</u>

U.S. sales during 2008 increased \$79.6 million compared to 2007 primarily due to increased sales of Angiomax as a result of increased demand by existing hospital customers, the addition of new hospital customers and the 8% price increases we implemented in August 2007 and January 2008. The increase in sales of Angiomax in the United States also reflects a \$1.4 million credit from our domestic wholesalers in

connection with our price increase announced in January 2008. Of the 31% increase in U.S. sales of Angiomax during 2008 compared to 2007, approximately 16% was attributable to price increases, 13% was related to hospital demand by existing hospital customers and the addition of new hospital customers and 2% was related to the \$1.4 million credit from our domestic wholesalers. The increase in U.S. sales in 2008 also includes \$0.4 million of net revenue from Cleviprex sales.

International net revenue increased \$9.7 million during 2008 compared to 2007 primarily as a result of a \$3.1 million increase in direct sales we made after assuming control of the distribution of Angiox in the Nycomed territory during the third quarter of 2008 and the \$2.2 million decrease of our reserve for existing inventory at Nycomed. As of December 31, 2008, we assumed control of the distribution of Angiox in the countries previously serviced by Nycomed. The remaining increase in international net revenue is primarily related to increased orders for Angiomax from our Canadian distributor.

During 2008, we recognized as revenue from collaborations approximately \$3.8 million of net revenue from sales made by Nycomed of approximately \$8.2 million under our transitional distribution agreement with Nycomed. Under the terms of this transitional distribution agreement, upon the sale by Nycomed to third parties of vials of Angiox, Nycomed pays us a specified percentage of Nycomed's net sales of Angiox, less the amount previously paid by Nycomed to us for the existing inventory. During 2007, we recognized as revenue from collaborations approximately \$2.5 million of net revenue from sales of Angiox made by Nycomed of approximately \$5.7 million under the transitional distribution agreement. The increase in revenue from collaborations is primarily due to the timing of when the Nycomed agreements were entered into and timing of when we assumed control of distribution of Angiox in the Nycomed territory.

*Cost of Revenue:*

As shown in the table below, cost of revenue in 2008 was \$88.4 million, or 25% of net revenue, compared to \$66.5 million, or 26% of net revenue, in 2007. Cost of revenue consisted of expenses in connection with the manufacture of Angiomax and Cleviprex sold, royalty expenses under our agreements with Biogen Idec and Health Research Inc. related to Angiomax and AstraZeneca related to Cleviprex and the logistics costs of selling Angiomax and Cleviprex, such as distribution, storage, and handling.

**Cost of Revenue**

<u>Cost of Revenue</u>	<u>Year Ended December 31,</u>			
	<u>2008</u>	<u>% of Total Cost</u>	<u>2007</u>	<u>% of Total Cost</u>
	<u>(In thousands)</u>		<u>(In thousands)</u>	
Manufacturing .....	\$22,518	25%	\$20,205	30%
Royalty .....	53,642	61%	40,318	61%
Logistics .....	12,195	14%	5,979	9%
<b>Total cost of revenue .....</b>	<b>\$88,355</b>	<b>100%</b>	<b>\$66,502</b>	<b>100%</b>

Cost of revenue increased \$21.9 million during 2008 compared to 2007. Approximately \$13.3 million of the total cost of revenue increase related to an increase in royalty expense due to higher Angiomax sales and approximately \$6.2 million of the increase related to an increase in logistics costs primarily related to higher sales of Angiomax and our costs associated with establishing our European distribution network. Manufacturing expenses increased \$2.3 million during 2008 compared to 2007. Approximately \$0.7 million of the increase was due to a write-off of one batch of Angiomax, \$0.5 million related to the inventory obsolescence reserve for Cleviprex and the remaining increase is primarily a result of producing more Angiomax to accommodate for higher sales. The decrease in cost of revenue as a percentage of net revenue is attributable to an increase in revenue from collaborations, net and an increase in U.S. sales of Angiomax.

*Research and Development Expenses:*

Research and development expenses increased by 37% to \$105.7 million for 2008, compared to \$77.3 million for 2007. The increase primarily reflects the acquisition of Curacyte Discovery in August 2008, which resulted in the inclusion in research and development expenses of \$21.4 million of acquisition related in-process research and development. The remaining increase in research and development expenses resulted primarily from increased expenses associated with our cangrelor clinical trials and increased business development expenses. The increase in research and development expenses was partially offset by decreased expenditures in connection with the development of Angiomax for additional indications and decreased research and development expenditures in connection with Cleviprex.

The following table identifies, for each of our major research and development projects, our spending for 2008 and 2007. Spending for past periods is not necessarily indicative of spending in future periods.

**Research and Development Spending**

<u>Research and Development</u>	<u>Year Ended December 31,</u>			
	<u>2008</u>	<u>% of</u>	<u>2007</u>	<u>% of</u>
	<u>(In thousands)</u>	<u>Total R&amp;D</u>	<u>(In thousands)</u>	<u>Total R&amp;D</u>
<b>Angiomax</b>				
Clinical trials . . . . .	\$ 4,959	5%	\$10,394	14%
Manufacturing development . . . . .	3,924	4%	703	1%
Administrative and headcount costs . . . . .	<u>3,711</u>	<u>3%</u>	<u>4,162</u>	<u>5%</u>
<b>Total Angiomax . . . . .</b>	<b>12,594</b>	<b>12%</b>	<b>15,259</b>	<b>20%</b>
<b>Cleviprex</b>				
Clinical trials . . . . .	3,031	3%	2,803	3%
Manufacturing development . . . . .	2,484	2%	2,890	4%
Administrative and headcount costs . . . . .	<u>6,214</u>	<u>6%</u>	<u>9,290</u>	<u>12%</u>
<b>Total Cleviprex . . . . .</b>	<b>11,729</b>	<b>11%</b>	<b>14,983</b>	<b>19%</b>
<b>Cangrelor</b>				
Clinical trials . . . . .	37,090	35%	30,135	39%
Manufacturing development . . . . .	2,661	3%	4,240	6%
Administrative and headcount costs . . . . .	<u>4,658</u>	<u>4%</u>	<u>3,971</u>	<u>5%</u>
<b>Total Cangrelor . . . . .</b>	<b>44,409</b>	<b>42%</b>	<b>38,346</b>	<b>50%</b>
<b>CU2010</b>				
Clinical trials . . . . .	—	0%		0%
Manufacturing development . . . . .	—	0%		0%
Administrative and headcount costs . . . . .	1,180	1%		0%
Acquisition related in-process research and development . . . . .	<u>21,373</u>	<u>20%</u>		<u>0%</u>
<b>Total CU2010 . . . . .</b>	<b>22,553</b>	<b>21%</b>		<b>0%</b>
<b>Other . . . . .</b>	<b>14,435</b>	<b>14%</b>	<b>8,667</b>	<b>11%</b>
<b>Total . . . . .</b>	<b><u>\$105,720</u></b>	<b><u>100%</u></b>	<b><u>\$77,255</u></b>	<b><u>100%</u></b>

*Angiomax*

Research and development spending related to Angiomax during 2008 decreased by approximately \$2.7 million compared to 2007. Angiomax clinical trial costs decreased by approximately \$5.4 million



primarily due to decreased expenditures in connection with the investigator initiated trial called HORIZONS AMI to study Angiomax use in adult AMI patients that we supported. During the third quarter of 2008, we incurred \$1.5 million in costs related to the final milestone payment in connection with HORIZONS AMI. The decrease in Angiomax clinical trial expenses was also due to decreased expenditures in connection with our 13,819 patient Phase 3 ACUITY trial. In 2007, clinical trial expenses incurred related to our Phase 3 ACUITY trial primarily related to data analysis. We incurred no clinical trial expense in 2008 related to ACUITY. Clinical trial expenses also decreased during 2008 due to reduced research and development expenses that we incurred in connection with a study of Angiomax in the pediatric setting that we began in the first half of 2007 in connection with a written request by the FDA. We completed the enrollment of 110 patients during the third quarter of 2008 and filed a clinical study report for the pediatric extension with the FDA in the second quarter of 2009. Costs incurred in connection with the pediatric study were approximately \$0.4 million less during 2008 compared to 2007.

Angiomax manufacturing development expenses during 2008 increased \$3.2 million compared to 2007, primarily due to product lifecycle management activities. Administrative and headcount costs decreased in 2008 primarily related to our efforts in 2007 to seek approval from the FDA of an additional indication for Angiomax for the treatment of patients with ACS based on results of our Phase 3 ACUITY trial. The FDA accepted this application to file in September 2007. In May 2008, we received a non-approvable letter from the FDA. In its letter, the FDA indicated that the basis of its decision involved the appropriate use and interpretation of the non-inferiority trials we relied on in support of our sNDA, including ACUITY trial. We disagree with the FDA on these issues and continue to evaluate how to respond to the FDA's views on the ACUITY trial

#### *Cleviprex*

Research and development expenditures for Cleviprex decreased approximately \$3.3 million during 2008 compared 2007. The decrease in research and development expenditures primarily reflected higher spending during 2007 in preparation for filing our NDA with the FDA, which we submitted in July 2007. On August 1, 2008, the FDA approved Cleviprex for the reduction of blood pressure when oral therapy is not feasible or not desirable. We launched the product in the United States in September 2008.

#### *Cangrelor*

Research and development expenditures related to cangrelor increased by approximately \$6.1 million in 2008 compared to 2007 as enrollment continued in our two pivotal Phase 3 clinical trials for the evaluation of cangrelor's effectiveness and safety in preventing ischemic events in patients who require PCI. Research and development spending associated with our CHAMPION-PCI and CHAMPION-PLATFORM trials increased during 2008 primarily due to an increase in the number of countries in which we were recruiting patients through contract research organizations for these trials. In March 2006, we commenced enrollment of our CHAMPION-PCI trial, which we designed to evaluate whether use of intravenous cangrelor is superior to use of clopidogrel tablets in patients undergoing PCI. We commenced enrollment in October 2006 of a second trial, called CHAMPION-PLATFORM, which compares cangrelor plus usual care to placebo plus usual care in patients who require PCI.

As of December 31, 2008, we had enrolled approximately 8,000 patients in our CHAMPION-PCI trial and approximately 4,100 patients in our CHAMPION-PLATFORM trial.

#### *CU2010*

In August 2008, we acquired Curacyte Discovery. We allocated approximately \$21.4 million of the purchase price for the acquisition to in-process research and development and expensed it during the third quarter of 2008.

*Other*

Spending in this category consists of infrastructure costs in support of our product development efforts, which includes expenses for data management, statistical analysis, analysis of pre-clinical data, analysis of pharmacokinetic-pharmacodynamic (PK/PD) data and product safety as well as expenses related to business development activities. We also incur business development expenses in connection with our efforts to evaluate early stage and late stage compounds for development and commercialization and other strategic opportunities. In 2008, spending in this category increased by \$5.8 million compared to the same period in 2007, primarily related to an increase in business development activities and increased headcount in our business development department.

*Selling, General and Administrative Expenses:*

	Year Ended December 31,			
	2008	2007	Change \$	Change %
	(In thousands)			
Selling, general and administrative expenses . . . . .	\$164,903	\$141,807	\$23,096	16.3%

Selling, general and administrative expenses increased by \$23.1 million to \$164.9 million for 2008, from \$141.8 million for 2007. The increase in selling, general and administrative expenses of \$23.1 million includes \$15.9 million of expenses incurred in preparation for the launch of Cleviprex, a \$13.1 million increase in expenses relating to marketing of Angiomax, \$3.8 million in fees related to the building of our business infrastructure in Europe, a \$14.5 million increase in costs related to headcount expansion, including the expansion of medical science, sales management and international operations teams and a \$6.5 million increase in stock-based compensation expense. The increase in selling, general and administrative expenses in 2008 was partially offset by the \$28.1 million of expenses incurred during the third quarter of 2007 related to the termination of the prior distribution agreement with Nycomed and our reacquisition of all the rights to develop, distribute and market Angiox in the Nycomed territory that we recorded as selling, general and administrative expenses in 2007.

*Other Income:*

	Year Ended December 31,		Change \$	Change %
	2008	2007		
	(In thousands)			
Other income . . . . .	\$5,235	\$10,653	\$(5,418)	(50.1)%

Other income, which is comprised of interest income and gains and losses on foreign currency transactions, decreased \$5.5 million to \$5.2 million for 2008, from \$10.7 million for 2007. Approximately \$3.9 million of the decrease in other income related to a decrease in interest income due to lower rates of return on our available for sale securities in 2008. The remaining decrease in other income related to losses on foreign currency transactions.

*(Provision for) Income Tax:*

	Year Ended December 31,		Change \$	Change %
	2008	2007		
	(In thousands)			
(Provision for) income tax . . . . .	\$(2,918)	\$(895)	\$2,023	226.0%

We recorded a provision for income taxes of \$2.9 million in 2008 and \$0.9 million in 2007 based on losses before income taxes of \$5.6 million and \$17.4 million for 2008 and 2007, respectively. The increase in the provision for income taxes in 2008 was attributable to the increase in foreign losses. We did not record a deferred tax benefit in 2008 or 2007 as we believed that the realization of the deferred tax assets associated with those losses was not more likely than not.

## Liquidity and Capital Resources

### *Sources of Liquidity*

Since our inception, we have financed our operations principally through the sale of common stock, sales of convertible promissory notes and warrants, interest income and revenues from sales of Angiomax. Except for 2006 and 2004, we have incurred losses on an annual basis since our inception. We had \$176.2 million in cash, cash equivalents and available for sale securities as of December 31, 2009.

### *Cash Flows*

As of December 31, 2009, we had \$72.2 million in cash and cash equivalents, as compared to \$81.0 million as of December 31, 2008. Our primary sources of cash during 2009 included \$1.0 million of net cash provided by operating activities and \$1.8 million in net cash provided by financing activities. These amounts were exceeded by the \$11.2 million in net cash that we used in investing activities.

Net cash provided by operating activities was \$1.0 million in 2009, compared to net cash provided by operating activities of \$38.1 million in 2008. The cash provided by operating activities in 2009 included a net loss of \$76.2 million, offset by non-cash items of \$80.4 million consisting primarily of a deferred tax provision of \$49.2 million, stock-based compensation expense of \$19.4 million and impairment of investment of \$5.0 million. Cash provided by operating activities in 2009 also included a decrease of \$3.2 million due to changes in working capital items.

The cash provided by operating activities in 2008 includes a decrease in cash flow from operations of \$8.5 million due to a net loss in 2008, offset by non-cash items of \$49.4 million consisting of in-process research and development charge of \$21.4 million in connection with the Curacyte Discovery acquisition, stock-based compensation expense of \$22.8 million and deferred tax provision of \$1.8 million. Cash provided by operating activities in 2008 also included a decrease of \$2.8 million due to changes in working capital items.

During 2009, \$11.2 million in net cash was used in investing activities, which reflected \$133.7 million used to purchase available for sale securities, a net cash expenditure of \$37.2 million in connection with the Targanta acquisition, an increase of restricted cash of \$1.7 million and \$0.3 million used to purchase fixed assets, offset by \$161.6 million in proceeds from the maturity and sale of available for sale securities.

During 2008, \$50.2 million in net cash was used in investing activities, which included \$161.8 million used to purchase available for sale securities, a net cash expenditure of \$23.5 million in connection with the Curacyte Discovery acquisition, \$19.4 million used to purchase fixed assets, a \$5.0 million investment in Eagle and \$2.0 million of milestone payments paid in connection with FDA approval of Cleviprex, offset by \$161.5 million in proceeds from the maturity and sale of available for sale securities.

We received \$1.8 million in 2009, \$5.5 million in 2008 and \$9.3 million in 2007, respectively, in net cash provided by financing activities, which consisted of proceeds to us from option exercises and purchases of stock under our employee stock purchase plan.

### *Funding Requirements:*

We expect to devote substantial resources to our research and development efforts and to our sales, marketing and manufacturing programs associated with Angiomax, Cleviprex and our products in development. Our funding requirements to support these efforts and programs depend upon many factors, including:

- the extent to which Angiomax is commercially successful globally;
- the outcome of our efforts to extend the patent term of the principal U.S. patent covering Angiomax and the degree of market exclusivity in the United States provided by our other U.S. patents covering Angiomax;

- the terms of any settlements with Biogen Idec or the two law firms with respect to the principal U.S. patent covering Angiomax and the PTO's denial of our application to extend the term of the patent;
- our ability to resupply the market with Cleviprex and the extent to which Cleviprex is commercially successful in the United States;
- the extent to which we can successfully establish a commercial infrastructure outside the United States;
- the cost of acquisitions or licensing of development-stage products, approved products, or businesses and strategic or licensing arrangements with companies that fit within our growth strategy;
- the progress, level, timing and cost of our research and development activities related to our clinical trials and non-clinical studies with respect to Angiomax, Cleviprex and our products in development;
- the cost and outcomes of regulatory submissions and reviews for approval of Cleviprex outside the United States and New Zealand and of our products in development globally;
- the continuation or termination of third-party manufacturing and sales and marketing arrangements;
- the size, cost and effectiveness of our sales and marketing programs globally;
- the amounts of our payment obligations to third parties as to Angiomax, Cleviprex and our products in development; and
- our ability to defend and enforce our intellectual property rights.

If our existing resources are insufficient to satisfy our liquidity requirements due to slower than anticipated sales of Angiomax and Cleviprex, or higher than anticipated costs globally, if we acquire additional product candidates or businesses, or if we determine that raising additional capital would be in our interest and the interests of our stockholders, we may sell equity or debt securities or seek additional financing through other arrangements. Any sale of additional equity or debt securities may result in dilution to our stockholders, and debt financing may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. We cannot be certain that public or private financing will be available in amounts or on terms acceptable to us, if at all. If we seek to raise funds through collaboration or licensing arrangements with third parties, we may be required to relinquish rights to products, product candidates or technologies that we would not otherwise relinquish or grant licenses on terms that may not be favorable to us. If we are unable to obtain additional financing, we may be required to delay, reduce the scope of, or eliminate one or more of our planned research, development and commercialization activities, which could harm our financial condition and operating results.

***Certain Contingencies:***

As we have previously disclosed, the U.S. Patent and Trademark Office, or PTO, rejected the application under the Hatch-Waxman Act for an extension of the term of U.S. Patent No. 5,196,404, or the '404 patent, the principal U.S. patent that covers Angiomax, beyond March 23, 2010 because in its view the application was not timely filed. We refer to such application herein as the patent extension filing. We have entered into agreements with the law firms involved in the patent extension filing that suspend the statute of limitations on any claims against them for failing to make a timely filing. We have entered into a similar agreement with Biogen Idec, one of our licensors for Angiomax, relating to any claims, including claims for damages and/or license termination, that Biogen Idec may bring relating to the patent extension filing. Such claims by Biogen Idec could have a material adverse effect on our financial condition, results of operations, liquidity or business. In the third quarter of 2009, we initiated discussions, which are still ongoing, with the law firms involved in the patent extension filing of the application and are currently in related discussions with Biogen Idec and HRI with respect to the possible resolution of potential claims among the parties.

## Contractual Obligations

Our long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. These include commitments related to purchases of inventory of our products, research and development service agreements, operating leases, selling, general and administrative obligations, increases to our restricted cash in connection with our lease of our principal office space in Parsippany, New Jersey and royalty and milestone payments due under our license agreements.

Future estimated contractual obligations as of December 31, 2009 are:

<u>Contractual Obligations (in thousands)</u>	<u>Total</u>	<u>Less Than 1 Year</u>	<u>1 - 3 Years</u>	<u>3 - 5 Years</u>	<u>More Than 5 Years</u>
Inventory related commitments . . . . .	\$ 47,966	\$27,897	\$20,069	\$ —	—
Research and development . . . . .	24,436	17,880	5,788	768	—
Operating leases . . . . .	69,187	6,997	13,630	10,458	38,102
Selling, general and administrative . . . . .	5,750	5,246	504	—	—
Unrecognized tax benefits . . . . .	167	—	167	—	—
Total contractual obligations . . . . .	<u>\$147,506</u>	<u>\$58,020</u>	<u>\$40,158</u>	<u>\$11,226</u>	<u>\$38,102</u>

All of the inventory related commitments included above are non-cancellable. Included within the inventory related commitments above are purchase commitments to Lonza Braine totaling \$26.1 million for 2010 and \$19.1 million for 2011 for Angiomax bulk drug substance. Of the total estimated contractual obligations for research and development and selling, general and administrative activities, \$3.6 million is non-cancellable.

In January 2009, we moved our principal offices to a new office building in Parsippany, New Jersey. The lease covering the new office building covers 173,146 square feet and expires January 2024. In connection with the move, we vacated our previous office space in Parsippany. The lease for our old office facility expires January 2013. In the second half of 2009, we sublet our old office space to two companies. The first sublease, for the second floor of our old office space, expires in March 2011, subject to renewal by the subtenant for up to three periods of six months each and thereafter for one period of four months, and the second sublease, covering the first floor of our previous office space, expires in January 2013. Additionally, certain other costs such as leasing commissions and legal fees will be expensed as incurred in conjunction with the sublease of the vacated office space.

Approximately 85% of the total operating lease commitments above relate to our new office building. Also included in total operating lease commitments are automobile leases, computer leases, the operating lease from our previous office space and other property leases that we entered into while expanding our European infrastructure.

In addition, we lease offices in Waltham, Massachusetts, Milton Park, Abingdon, United Kingdom; Zurich, Switzerland; Paris, France; Rome Italy; Munich, Germany; Leipzig, Germany; and Montreal, Canada. Aggregate rent expense for these offices was approximately \$7.5 million in 2009, \$2.2 million in 2008 and \$1.6 million in 2007.

In addition to the amounts shown in the above table, we are contractually obligated to make potential future success-based development, regulatory and commercial milestone payments and royalty payments in conjunction with collaborative agreements or acquisitions we have entered into with third-parties. These payments are contingent upon the occurrence of certain future events and, given the nature of these events, it is unclear when, if ever, we may be required to pay such amounts. These contingent payments have not been included in the table above or recorded on our consolidated balance sheets. Further, the timing of any future payment is not reasonable estimable. As such, obligations related to the acquisition of Targanta which occurred in February 2009, including contingent cash payments up to approximately \$90.4 million that would be owed to former Targanta shareholders under our merger agreement with Targanta, are not included in the above.

## Recent Accounting Pronouncements

Effective January 1, 2009, we adopted the revised authoritative guidance on business combinations which changed existing practice, in part, as follows: contingent consideration arrangements are now fair valued at the acquisition date and included on that basis in the purchase price consideration; transaction costs are now expensed as incurred, rather than capitalized as part of the purchase price; reversal of valuation allowances created in purchase accounting are now recorded through the income tax provision; and in order to accrue for a restructuring plan in purchase accounting, all authoritative guidance would have to be met at the acquisition date. We accounted for the Targanta acquisition under this revised authoritative guidance; see note 6 to our consolidated financial statements included in this annual report on Form 10-K.

In April 2009, the Financial Accounting Standards Board, or FASB, issued FASB Staff Position No. FAS 107-1 and APB 28-1, "Interim Disclosures about Fair Value of Financial Instruments," which was later superseded by the FASB Accounting Standards Codification, or ASC, also known collectively as the "FASB Codification," and included in ASC topic 825 which requires disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. This guidance is effective for interim reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. We adopted this accounting pronouncement as of and for the period ended June 30, 2009 and this adoption did not have a material impact on our financial statements.

In April 2009, the FASB issued FASB Staff Position No. FAS 115-2 and FAS 124-2, "Recognition and Presentation of Other-Than-Temporary Impairments," which was later superseded by the FASB Codification and included in ASC topic 320, which amends the other-than-temporary impairment guidance in GAAP for debt securities to make the guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. This guidance is effective for interim and annual reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. We adopted this accounting pronouncement as of and for the period ended June 30, 2009 and it did not have a material impact on our financial statements.

In May 2009, the FASB issued Statement of Financial Accounting Standard, or SFAS, No. 165, "Subsequent Events", which was later superseded by the FASB Codification and included in ASC topic 855-10, or ASC 855-10. ASC 855-10 is intended to establish general standards of accounting for, and disclosure of, events that occur after the balance sheet date but before financial statements are issued or are available to be issued. ASC 855-10 requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for selecting that date, including whether that date represents the date the financial statements were issued or were available to be issued. ASC 855-10 is effective for interim or annual financial periods ending after June 15, 2009. We adopted this accounting pronouncement as of and for the period ended June 30, 2009 and it did not have a material impact on our financial statements.

In June 2009, the FASB issued SFAS No. 167, "Amendments to FASB Interpretation No. 46(R)", which was later superseded by the FASB Codification and included in ASC topic 810-10, or ASC 810-10, which modifies how a company determines when an entity that is insufficiently capitalized or is not controlled through voting (or similar rights) should be consolidated. ASC 810-10 clarifies that the determination of whether a company is required to consolidate an entity is based on, among other things, an entity's purpose and design and a company's ability to direct the activities of the entity that most significantly impact the entity's economic performance. ASC 810-10 requires an ongoing reassessment of whether a company is the primary beneficiary of a variable interest entity. ASC 810-10 also requires additional disclosures about a company's involvement in variable interest entities and any significant changes in risk exposure due to that involvement. This guidance is effective for fiscal years beginning after November 15, 2009 and is effective for us on January 1, 2010. We do not expect that the adoption of ASC 810-10 will have a material impact on our results of operations or financial.

In June 2009, the FASB issued SFAS No. 168, "The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles", a replacement of FASB Statement No. 162. This statement modifies the GAAP hierarchy by establishing only two levels of GAAP, authoritative and

nonauthoritative accounting literature. Effective July 2009, the FASB Codification is considered the single source of authoritative U.S. accounting and reporting standards, except for additional authoritative rules and interpretive releases issued by the SEC. Nonauthoritative guidance and literature would include, among other things, FASB Concepts Statements, American Institute of Certified Public Accountants Issue Papers and Technical Practice Aids and accounting textbooks. The FASB Codification was developed to organize GAAP pronouncements by topic so that users can more easily access authoritative accounting guidance. It is organized by topic, subtopic, section, and paragraph, each of which is identified by a numerical designation. This statement applied beginning in third quarter 2009. All accounting references have been updated, and therefore SFAS references have been replaced with ASC references.

In August 2009, the FASB issued the FASB Codification update No. 2009-05 "Fair Value Measurements and Disclosures." The update is to subtopic ASC 820-10, Fair Value Measurements and Disclosures-Overall, for the fair value measurement of liabilities. The purpose of this update is to reduce ambiguity in financial reporting when measuring fair value of liabilities. The guidance in the update was effective for us during the three months ending September 30, 2009 and did not have a material impact on our financial statements.

### **Application of Critical Accounting Estimates**

The discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect our reported assets and liabilities, revenues and expenses, and other financial information. Actual results may differ significantly from these estimates under different assumptions and conditions. In addition, our reported financial condition and results of operations could vary due to a change in the application of a particular accounting standard.

We regard an accounting estimate or assumption underlying our financial statements as a "critical accounting estimate" where:

- the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and
- the impact of the estimates and assumptions on financial condition or operating performance is material.

Our significant accounting policies are more fully described in note 2 to our consolidated financial statements included in this annual report on Form 10-K. Not all of these significant accounting policies, however, require that we make estimates and assumptions that we believe are "critical accounting estimates." We have discussed our accounting policies with the audit committee of our board of directors, and we believe that our estimates relating to revenue recognition, inventory, stock-based compensation and income taxes described below are "critical accounting estimates."

#### ***Revenue Recognition***

*Product Sales.* We distribute Angiomax and Cleviprex in the United States through a sole source distribution model. Under this model, we sell Angiomax and Cleviprex to our sole source distributor, ICS, which then sells Angiomax and Cleviprex to a limited number of national medical and pharmaceutical wholesalers with distribution centers located throughout the United States and in certain cases, directly to hospitals. Our agreement with ICS, which we initially entered into February 2007, provides that ICS will be our exclusive distributor of Angiomax and Cleviprex in the United States. Under the terms of this fee-for-service agreement, ICS assumes all credit and inventory risks, is subject to our standard return policy, places orders with us for sufficient quantities of Angiomax and Cleviprex to maintain an appropriate level of inventory based on our customers' historical purchase volumes and has sole responsibility for determining the prices at which it sells Angiomax and Cleviprex, subject to specified limitations in the agreement. The agreement terminates on February 28, 2011, but will automatically renew for additional one-year periods unless either party gives notice at least 120 days prior to the automatic extension. We may also terminate the

agreement at any time and for any reason upon prior written notice to ICS and payment of a termination fee of between \$100,000 and \$250,000.

Outside of the United States, we sell Angiomax either directly to hospitals or to wholesalers or international distributors, which then sell Angiomax to hospitals. We had deferred revenue of \$0.4 million as of December 31, 2009 and December 31, 2008 associated with sales of Angiomax to wholesalers outside of the United States. We recognize revenue from such sales when hospitals purchase the product.

We do not recognize revenue from product sales until there is persuasive evidence of an arrangement, delivery has occurred, the price is fixed and determinable, the buyer is obligated to pay us, the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from us, we have no obligation to bring about the sale of the product, the amount of returns can be reasonably estimated and collectability is reasonably assured.

We began selling Cleviprex in the United States in September 2008. Initial gross wholesaler orders of Cleviprex in the United States in the third quarter of 2008 totaled \$10.0 million. We recorded this amount as deferred revenue as we could not estimate certain adjustments to gross revenue, including returns. Under this deferred revenue model, we do not recognize revenue upon product shipment to ICS. Instead, upon product shipment, we invoice ICS, record deferred revenue at gross invoice sales price, classify the cost basis of the product held by ICS as finished goods inventory held by others and include such cost basis amount within prepaid expenses and other current assets on our consolidated balance sheets. We currently recognize the deferred revenue when hospitals purchase product and will do so until such time that we have sufficient information to develop reasonable estimates of expected returns and other adjustments to gross revenue. When such estimates are developed, we expect to recognize Cleviprex revenue upon shipment to ICS in the same manner as we recognize Angiomax revenue. During the third quarter of 2009, we reduced our contract price for Cleviprex, which had the effect of reducing the deferred revenue by approximately \$4.0 million. In the fourth quarter of 2009, we announced a voluntary recall of 11 lots of Cleviprex, including any remaining unsold inventory associated with its initial wholesaler orders which resulted in a reduction of deferred revenue of approximately \$2.0 million. We recognized \$3.0 million of revenue associated with Cleviprex during 2009 related to purchases by hospitals.

We record allowances for chargebacks and other discounts or accruals for product returns, rebates and fee-for-service charges at the time of sale, and reports revenue net of such amounts. In determining the amounts of certain allowances and accruals, we must make significant judgments and estimates. For example, in determining these amounts, we estimate hospital demand, buying patterns by hospitals and group purchasing organizations from wholesalers and the levels of inventory held by wholesalers and by ICS. Making these determinations involves estimating whether trends in past wholesaler and hospital buying patterns will predict future product sales. We receive data periodically from ICS and wholesalers on inventory levels and levels of hospital purchases and we consider this data in determining the amounts of these allowances and accruals.

The nature of our allowances and accruals requiring critical estimates, and the specific considerations we use in estimating our amounts are as follows.

- *Product returns.* Our customers have the right to return any unopened product during the 18-month period beginning six months prior to the labeled expiration date and ending 12 months after the labeled expiration date. As a result, in calculating the accrual for product returns, we must estimate the likelihood that product sold might not be used within six months of expiration and analyze the likelihood that such product will be returned within 12 months after expiration. We consider all of these factors and adjust the accrual periodically throughout each quarter to reflect actual experience. When customers return product, they are generally given credit against amounts owed. The amount credited is charged to our product returns accrual.

In estimating the likelihood of product being returned, we rely on information from ICS and wholesalers regarding inventory levels, measured hospital demand as reported by third-party sources and internal sales data. We also consider the past buying patterns of ICS and wholesalers, the estimated



remaining shelf life of product previously shipped, the expiration dates of product currently being shipped, price changes of competitive products and introductions of generic products.

At December 31, 2009 and December 31, 2008, our accrual for product returns was \$3.8 million and \$1.0 million, respectively. Included within the accrual at December 31, 2009 was a reserve of \$1.3 million that we established related to the Cleviprex product recall which occurred in December 2009. Included within the accrual at December 31, 2008 was a reserve of \$0.8 million that we established for existing inventory at Nycomed that Nycomed had the right to return at any time. In July 2009, we reimbursed Nycomed \$0.8 million for the final amount of inventory held by Nycomed at December 31, 2008. A 10% change in our accrual for product returns would have had an approximate \$0.4 million effect on our reported net revenue for the year ended December 31, 2009.

- *Chargebacks and rebates.* Although we primarily sell products to ICS in the United States, we typically enter into agreements with hospitals, either directly or through group purchasing organizations acting on behalf of their hospital members, in connection with the hospitals' purchases of products.

Based on these agreements, most of our hospital customers have the right to receive a discounted price for products and volume-based rebates on product purchases. In the case of discounted pricing, we typically provide a credit to ICS, or a chargeback, representing the difference between ICS's acquisition list price and the discounted price. In the case of the volume-based rebates, we typically pay the rebate directly to the hospitals.

As a result of these agreements, at the time of product shipment, we estimate the likelihood that product sold to ICS might be ultimately sold to a contracting hospital or group purchasing organization. We also estimate the contracting hospital's or group purchasing organization's volume of purchases.

We base our estimates on industry data, hospital purchases and the historic chargeback data we receive from ICS, most of which ICS receives from wholesalers, which detail historic buying patterns and sales mix for particular hospitals and group purchasing organizations, and the applicable customer chargeback rates and rebate thresholds.

Our allowance for chargebacks was \$4.7 million and \$1.2 million at December 31, 2009 and December 31, 2008, respectively. A 10% change in our allowance for chargebacks would have had an approximate \$0.5 million effect on our reported net revenue for the year ended December 31, 2009. Our accrual for rebates was \$0.0 million at December 31, 2009 and \$0.4 million at December 31, 2008.

- *Fees-for-service.* We offer discounts to certain wholesalers and ICS based on contractually determined rates for certain services. We estimate our fee-for-service accruals and allowances based on historical sales, wholesaler and distributor inventory levels and the applicable discount rate. Our discounts are accrued at the time of the sale and are typically settled with the wholesalers or ICS within 60 days after the end of each respective quarter. Our fee-for-service accruals and allowances were \$3.1 million and \$2.0 million at December 31, 2009 and December 31, 2008, respectively. A 10% change in our fee-for-service accruals and allowances would have had an approximate \$0.3 million effect on our net revenue for the year ended December 31, 2009.

We have adjusted our allowances for chargebacks and accruals for product returns, rebates and fees-for-service in the past based on actual sales experience, and we will likely be required to make adjustments to these allowances and accruals in the future. We continually monitor our allowances and accruals and makes adjustments when we believe actual experience may differ from our estimates. The allowances included in the table below reflect these adjustments.

The following table provides a summary of activity with respect to our sales allowances and accruals during 2009, 2008 and 2007 (amounts in thousands):

	<u>Returns</u>	<u>Chargebacks</u>	<u>Rebates</u>	<u>Fees-for-Service</u>
<b>Balance at January 1, 2007</b> .....	\$ 401	\$ 328	\$ 834	\$ 1,774
Allowances for sales during 2007 .....	113	4,386	4,546	4,507
Allowances for prior year sales .....	60	99	25	—
Allowances for sales in Nycomed territory .....	2,959	—	—	—
Actual credits issued for prior year's sales .....	(459)	(427)	(849)	(929)
Actual credits issued for sales during 2007 .....	<u>(14)</u>	<u>(3,789)</u>	<u>(2,894)</u>	<u>(3,695)</u>
<b>Balance at December 31, 2007</b> .....	3,060	597	1,662	1,657
Allowances for sales during 2008 .....	138	5,628	1,413	6,562
Allowances for prior year sales .....	159	123	—	—
Allowances for sales in Nycomed territory .....	—	—	—	—
Actual credits issued for prior year's sales .....	(261)	(720)	(1,397)	(721)
Actual credits issued for prior year's sales in Nycomed territory .....	(2,121)	—	—	—
Actual credits issued for sales during 2008 .....	<u>—</u>	<u>(4,442)</u>	<u>(1,247)</u>	<u>(5,542)</u>
<b>Balance at December 31, 2008</b> .....	975	1,186	431	1,956
Allowances for sales during 2009 .....	3,764	13,439	212	9,582
Allowances for prior year sales .....	274	—	—	—
Actual credits issued for prior year's sales .....	(1,249)	(1,174)	(275)	(1,670)
Actual credits issued for sales during 2009 .....	<u>—</u>	<u>(8,787)</u>	<u>(357)</u>	<u>(6,743)</u>
<b>Balance at December 31, 2009</b> .....	<u>\$ 3,764</u>	<u>\$ 4,664</u>	<u>\$ 11</u>	<u>\$ 3,125</u>

Included within the 2007 allowances above is the reserve of \$3.0 million that we recorded during the fourth quarter of 2007 for the existing inventory at Nycomed which we did not believe would be sold prior to the termination of our transitional distribution agreement with Nycomed and would be subject to purchase in accordance with the agreement. During 2008, we reduced the reserve by \$2.2 million as Nycomed sold a portion of the existing inventory during the year. Such amount is included within the 2008 allowances above. In 2009, we reimbursed Nycomed \$0.8 million for the final amount of inventory held by Nycomed at December 31, 2008.

*International Distributors.* Under our agreements with our primary international distributors, we sell Angiomax to these distributors at a fixed price. The established price is typically determined once per year, prior to the first shipment of Angiomax to the distributor each year. The minimum selling price used in determining the price is 50% of the average net unit selling price.

Revenue from the sale of products during 2007 includes the amortization of milestone payments. These milestone payments are recorded as deferred revenue until contractual performance obligations have been satisfied, and they are typically recognized ratably over the term of these agreements. When the period of deferral cannot be specifically identified from the contract, we must estimate the period based upon other critical factors contained within the contract. We review these estimates at least annually, which could result in a change in the deferral period. In connection with the Nycomed transaction (described in note 7 to our consolidated financial statements included in this annual report on Form 10-K), we wrote-off approximately \$2.7 million of deferred revenue during the third quarter of 2007, which amount represented the unamortized portion of deferred revenue related to milestone payments received from Nycomed in 2004 and 2002.

Revenue associated with sales to our international distributors during 2009, 2008 and 2007 was \$4.4 million, \$6.6 million and \$0.1 million, respectively. During 2007, international net revenue was reduced by \$3.0 million, which represented a reserve for existing inventory at Nycomed because we did not believe

that such inventory would be sold by Nycomed prior to the termination of our transitional distribution agreement with Nycomed and because such inventory was subject to return. During 2008, we reduced the Nycomed inventory reserve by \$2.2 million as Nycomed sold a portion of our existing inventory during the year. Such amounts are included in the \$6.6 million of revenue associated with sales to our international distributors during 2008. As a result, we reduced our reserve for existing inventory to \$0.8 million, which resulted in an increase to international net revenue. We reimbursed Nycomed \$0.8 million in July 2009 for the final amount of inventory held by Nycomed at December 31, 2008.

*Revenue from Collaborations.* Under the terms of the transitional distribution agreement with Nycomed, we were entitled to receive a specified percentage of Nycomed's net sales of Angiox to third parties. In the event the Angiox sold was purchased by Nycomed from us prior to July 1, 2007, the amount we were entitled to receive in connection with such sale was reduced by the amount previously paid by Nycomed to us for such product. Accordingly, revenue related to the transitional distribution agreement with Nycomed entered into in 2007, under which Nycomed provided product distribution services through the second half of 2008, was not recognized until the product was sold by Nycomed to a hospital customer. For the year ended December 31, 2008, we recorded \$3.8 million of net revenue from sales made by Nycomed of approximately \$8.2 million under the transitional distribution agreement. We recorded such amount as revenue from collaborations and included it in net revenue on our consolidated statements of operations. Because we assumed control of the distribution of Angiox in all countries in the Nycomed territory by December 31, 2008, we did not have any revenue from collaborations during the year ended December 31, 2009.

### ***Inventory***

We record inventory upon the transfer of title from our vendors. Inventory is stated at the lower of cost or market value and valued using first-in, first-out methodology. Angiomax and Cleviprex bulk substance is classified as raw materials and its costs are determined using acquisition costs from our contract manufacturers. We record work-in-progress costs of filling, finishing and packaging against specific product batches. We obtain all of our Angiomax bulk drug substance from Lonza Braine, S.A. Under the terms of our agreement with Lonza Braine, we provide forecasts of our annual needs for Angiomax bulk substance 18 months in advance. We also have a separate agreement with Ben Venue Laboratories, Inc. for the fill-finish of Angiomax drug product. We obtain all of our Cleviprex bulk drug substance from Johnson Matthey Pharma Services and also have a separate agreement with Hospira, Inc. for the fill-finish of Cleviprex drug product.

We review inventory, including inventory purchase commitments, for slow moving or obsolete amounts based on expected revenues. As of December 31, 2008, we had an inventory obsolescence reserve of \$0.5 million related to Cleviprex. As of December 31, 2009, the obsolescence reserve related to Cleviprex was reduced to zero. If annual revenues are less than expected, we may be required to make additional allowances for excess or obsolete inventory in the future.

### ***Stock-Based Compensation***

We have established equity compensation plans for our employees, directors and certain other individuals. All grants and terms are authorized by our Board of Directors or the Compensation Committee of our Board of Directors, as appropriate. We may grant non-qualified stock options, restricted stock awards, stock appreciation rights and other stock-based awards under our Amended & Restated 2004 Stock Incentive Plan. From January 2008 to May 2008, we granted non-qualified stock options under our 2007 Equity Inducement Plan to new employees as an inducement to their entering into employment with us. We currently grant non-qualified stock options under our 2009 Equity Inducement Plan, which was adopted in April 2009, to new employees as an inducement to their entering into employment with us.

Effective January 1, 2006, we adopted the fair value recognition provisions of FASB Statement No. 123 (revised 2004) "Share-Based Payment", which was later superseded by the FASB Codification and included in ASC topic 718-10, or ASC 718-10, and recognizes expense using the accelerated expense attribution method. ASC 718-10 requires companies to recognize compensation expense in an amount equal to the fair value of all share-based awards granted to employees.

We estimate the fair value of each option on the date of grant using the Black-Scholes closed-form option-pricing model based on assumptions for the expected term of the stock options, expected volatility of our common stock, and prevailing interest rates. ASC 718-10 also requires us to estimate forfeitures in calculating the expense relating to stock-based compensation as opposed to only recognizing forfeitures and the corresponding reduction in expense as they occur.

We have based our assumptions on the following:

<u>Assumption</u>	<u>Method of Estimating</u>
<ul style="list-style-type: none"> <li>• Estimated expected term of options</li> </ul>	<ul style="list-style-type: none"> <li>• Employees' historical exercise experience and, at times, estimates of future exercises of unexercised options based on the midpoint between the vesting date and end of the contractual term</li> </ul>
<ul style="list-style-type: none"> <li>• Expected volatility</li> </ul>	<ul style="list-style-type: none"> <li>• Historical price of our common stock and the implied volatility of the stock of our peer group</li> </ul>
<ul style="list-style-type: none"> <li>• Risk-free interest rate</li> </ul>	<ul style="list-style-type: none"> <li>• Yields of U.S. Treasury securities corresponding with the expected life of option grants</li> </ul>
<ul style="list-style-type: none"> <li>• Forfeiture rates</li> </ul>	<ul style="list-style-type: none"> <li>• Historical forfeiture data</li> </ul>

Of these assumptions, the expected term of the option and expected volatility of our common stock are the most difficult to estimate since they are based on the exercise behavior of the employees and expected performance of our common stock. Increases in the term and the volatility of our common stock will generally cause an increase in compensation expense.

### ***Income Taxes***

Our annual effective tax rate is based on pre-tax earnings adjusted for differences between GAAP and income tax accounting, existing statutory tax rates, limitations on the use of net operating loss and tax credit carryforwards and tax planning opportunities available in the jurisdictions in which we operate.

In accordance with ASC 740, we use a two-step approach for recognizing and measuring tax benefits taken or expected to be taken in a tax return and disclosures regarding uncertainties in income tax positions. The first step is recognition: we determine whether it is more likely than not that a tax position will be sustained upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position. In evaluating whether a tax position has met the more-likely-than-not recognition threshold, we presume that the position will be examined by the appropriate taxing authority that has full knowledge of all relevant information. The second step is measurement: we measure a tax position that meets the more-likely-than-not recognition threshold to determine the amount of benefit to recognize in our financial statements. The tax position is measured at the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement. Significant judgment is required in evaluating our tax position. Settlement of filing positions that may be challenged by tax authorities could impact the income tax position in the year of resolution. Our current tax liability is included within accrued expenses in the consolidated balance sheets.

On a periodic basis, we evaluate the realizability of our deferred tax assets net of deferred tax liabilities and will adjust such amounts in light of changing facts and circumstances, including but not limited to future projections of taxable income, tax legislation, rulings by relevant tax authorities, tax planning strategies and the progress of ongoing tax audits. We consider all available evidence, both positive and negative, to determine whether, based on the weight of that evidence, a valuation allowance is needed to reduce the net deferred tax assets to the amount that is more likely than not to be realized. At December 31, 2009, we provided for a full

valuation allowance of \$171.4 million. In determining this valuation allowance, we evaluated and considered such positive and negative evidence as:

*Positive:*

- our deferred tax assets primarily relate to U.S. net operating losses, the oldest of which will not expire until 2020;
- our second product, Cleviprex, was approved for sale in the United States; we expect it to generate revenue well past the term of the principal U.S. patent covering Angiomax;
- while unsettled, if legislative actions in Congress provide the PTO with discretion to consider patent extension applications filed late unintentionally under the Hatch-Waxman Act, we expect future operations and profit levels during the period of Angiomax exclusivity to be positively impacted;

*Negative:*

- since inception, except for 2004 and 2006, we have incurred net losses on an annual basis, as of December 31, 2009, we had an accumulated deficit of approximately \$344.2 million;
- for the most recent three years, our cumulative U.S. net loss before taxes totaled approximately \$37.1 million;
- our primary revenue generating product, Angiomax, may face generic competition with the expiration of its market exclusivity as early as September 23, 2010;
- we are currently involved in patent infringement litigation with three companies; as a result, our future operations and profitability are highly uncertain.

Based on this evaluation and consideration of positive and negative evidence, we determined that the weight of the evidence required a \$171.4 million valuation allowance to fully reserve against our deferred tax assets to the amount that is more likely than not to be realized. In the fourth quarter of 2009, we recorded a \$55.5 million income tax expense to increase our valuation allowance to \$171.4 million.

#### **Item 7A. Quantitative and Qualitative Disclosure About Market Risk**

Market risk is the risk of change in fair value of a financial instrument due to changes in interest rates, equity prices, creditworthiness, financing, exchange rates or other factors. Our primary market risk exposure relates to changes in interest rates in our cash, cash equivalents and available for sale securities. We place our investments in high-quality financial instruments, primarily money market funds, corporate debt securities, asset backed securities and U.S. government agency notes with maturities of less than two years, which we believe are subject to limited interest rate and credit risk. We currently do not hedge interest rate exposure. At December 31, 2009 we held \$176.2 million in cash, cash equivalents and available for sale securities which had an average interest rate of approximately 0.39%. A 10 basis point change in such average interest rate would have had an approximate \$0.1 million impact on our interest income. Of \$176.2 million, approximately \$172.5 million of cash, cash equivalents and available for sale securities were due on demand or within one year and had an average interest rate of approximately of 0.38%. The remaining \$3.7 million were due within two years and had an average interest rate of approximately 0.48%.

Most of our transactions are conducted in U.S. dollars. We do have certain agreements with parties located outside the United States. Transactions under certain of these agreements are conducted in U.S. dollars, subject to adjustment based on significant fluctuations in currency exchange rates. Transactions under certain other of these agreements are conducted in the local foreign currency. As of December 31, 2009, we had receivables denominated in currencies other than the U.S. dollar. A 10.0% change would have had an approximate \$0.6 million impact on our other income and cash.

## **Item 8. Financial Statements and Supplementary Data**

All financial statements and schedules required to be filed hereunder are filed as Appendix A to this annual report on Form 10-K and incorporated herein by this reference.

## **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

## **Item 9A. Controls and Procedures**

### ***Disclosure Controls and Procedures***

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2009. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2009, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

### ***Management’s Annual Report on Internal Control Over Financial Reporting***

The report required to be filed hereunder is included in Appendix A to this annual report on Form 10-K and incorporated herein by this reference.

### ***Attestation Report of Independent Registered Public Accounting Firm***

The report required to be filed hereunder is included in Appendix A to this annual report on Form 10-K and incorporated herein by this reference.

### ***Changes in Internal Control Over Financial Reporting***

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended December 31, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART III**

Pursuant to Paragraph G(3) of the General Instructions to Form 10-K, the information required by Part III (Items 10, 11, 12, 13 and 14) is being incorporated by reference herein from our proxy statement to be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year ended December 31, 2009 in connection with our 2010 annual meeting of stockholders. We refer to such proxy statement herein as our 2010 Proxy Statement.

**Item 10. Directors, Executive Officers and Corporate Governance**

The information required by this item will be contained in our 2010 Proxy Statement under the captions “Discussion of Proposals,” “Information About Corporate Governance,” “Information About Our Executive Officers” and “Section 16(a) Beneficial Ownership Reporting Compliance” and is incorporated herein by this reference.

We have adopted a code of business conduct and ethics applicable to all of our directors and employees, including our principal executive officer, principal financial officer and our controller. The code of business conduct and ethics is available on the corporate governance section of “Investor Relations” of our website, *www.themedicinescompany.com*.

Any waiver of the code of business conduct and ethics for directors or executive officers, or any amendment to the code that applies to directors or executive officers, may only be made by the board of directors. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this code of ethics by filing a Form 8-K disclosing such waiver, or, to the extent permitted by applicable NASDAQ regulations, by posting such information on our website, at the address and location specified above. To date, no such waivers have been requested or granted.

**Item 11. Executive Compensation**

The information required by this item will be contained in our 2010 Proxy Statement under the captions “Information About Corporate Governance” and “Information About Our Executive Officers” and is incorporated herein by this reference.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The information required by this item will be contained in our 2010 Proxy Statement under the captions “Principal Stockholders,” “Information About Our Executive Officers” and “Equity Compensation Plan Information” and is incorporated herein by this reference.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

The information required by this item will be contained in our 2010 Proxy Statement under the caption “Information About Corporate Governance” and “Information About Our Executive Officers” and is incorporated herein by this reference.

**Item 14. Principal Accountant Fees and Services**

The information required by this item will be contained in our 2010 Proxy Statement under the caption “Independent Registered Public Accounting Firm Fees and Other Matters” and “Discussion of Proposals” and is incorporated herein by this reference.

## PART IV

### Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this annual report:

(1) *Financial Statements.* The Consolidated Financial Statements are included as Appendix A hereto and are filed as part of this annual report. The Consolidated Financial Statements include:

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(2) *Financial Statement Schedule.* The financial statement schedule following the Notes to Consolidated Financial Statements is filed as part of this annual report. All other schedules are omitted because they are not applicable or are not required, or because the required information is included in the consolidated financial statements or notes filed as part of this annual report

(3) *Exhibits.* The exhibits set forth on the Exhibit Index following the signature page to this annual report are filed as part of this annual report. This list of exhibits identifies each management contract or compensatory plan or arrangement required to be filed as an exhibit to this annual report.





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THE MEDICINES COMPANY**

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## **Management's Report on Consolidated Financial Statements and Internal Control over Financial Reporting**

The management of The Medicines Company has prepared, and is responsible for, The Medicines Company's consolidated financial statements and related footnotes. These consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles.

The Medicines Company's management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of the Company's principal executive and principal financial officers and effected by the Company's board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of The Medicines Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of The Medicines Company are being made only in accordance with authorizations of management and directors of The Medicines Company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of The Medicines Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Medicines Company's management assessed the Company's internal control over financial reporting as of December 31, 2009. Management's assessment was based upon the criteria established in "Internal Control — Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its assessment, management concluded that, as of December 31, 2009, The Medicines Company's internal control over financial reporting is effective based on those criteria.

/s/ Clive A. Meanwell

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*Chairman and  
Chief Executive Officer*

/s/ Glenn P. Sblendorio

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*Executive Vice President and  
Chief Financial Officer*

Dated March 16, 2010

## **Report of Independent Registered Public Accounting Firm**

### **The Board of Directors and Stockholders of The Medicines Company**

We have audited the accompanying consolidated balance sheets of The Medicines Company as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2009. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of The Medicines Company at December 31, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects, the information set forth therein.

As discussed in Note 2 to the consolidated financial statements, effective January 1, 2009 the Company adopted revised authoritative guidance related to accounting for business combinations and effective January 1, 2007 the Company changed its method of accounting for uncertainty in income taxes.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), The Medicines Company's internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 16, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

MetroPark, NJ  
March 16, 2010

**Report of Independent Registered Public Accounting Firm  
on Internal Control over Financial Reporting**

**The Board of Directors and Stockholders of The Medicines Company**

We have audited The Medicines Company's internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). The Medicines Company's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Consolidated Financial Statements and Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, The Medicines Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2009 consolidated financial statements of The Medicines Company and our report dated March 16, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

MetroPark, NJ  
March 16, 2010

**THE MEDICINES COMPANY**  
**CONSOLIDATED BALANCE SHEETS**

	December 31,	
	2009	2008
	(In thousands, except share and per share amounts)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents . . . . .	\$ 72,225	\$ 81,018
Available for sale securities . . . . .	103,966	135,188
Accrued interest receivable . . . . .	922	1,336
Accounts receivable, net of allowances of approximately \$6.4 million and \$1.9 million at December 31, 2009 and 2008 . . . . .	29,789	33,657
Inventory . . . . .	25,836	28,229
Prepaid expenses and other current assets . . . . .	9,984	16,402
Total current assets . . . . .	242,722	295,830
Fixed assets, net . . . . .	25,072	27,331
Intangible assets, net . . . . .	84,678	16,349
Goodwill . . . . .	14,934	—
Restricted cash . . . . .	7,049	5,000
Deferred tax assets . . . . .	—	37,657
Other assets . . . . .	321	5,237
Total assets . . . . .	\$ 374,776	\$ 387,404
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable . . . . .	\$ 8,431	\$ 12,968
Accrued expenses . . . . .	77,088	61,028
Deferred revenue . . . . .	1,100	9,612
Total current liabilities . . . . .	86,619	83,608
Contingent purchase price . . . . .	23,667	—
Deferred tax liabilities . . . . .	18,395	—
Other liabilities . . . . .	5,706	5,771
Total liabilities . . . . .	134,387	89,379
Stockholders' equity:		
Preferred stock, \$1.00 par value per share, 5,000,000 shares authorized; no shares issued and outstanding . . . . .	—	—
Common stock, \$.001 par value per share, 125,000,000 shares authorized; 52,830,376 and 52,280,006 issued and outstanding at December 31, 2009 and 2008, respectively . . . . .	53	52
Additional paid-in capital . . . . .	584,678	565,083
Accumulated deficit . . . . .	(344,177)	(267,948)
Accumulated other comprehensive (loss) income . . . . .	(165)	838
Total stockholders' equity . . . . .	240,389	298,025
Total liabilities and stockholders' equity . . . . .	\$ 374,776	\$ 387,404

See accompanying notes to consolidated financial statements.

**THE MEDICINES COMPANY**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	<u>Year Ended December 31,</u>		
	<u>2009</u>	<u>2008</u>	<u>2007</u>
	(In thousands, except per share amounts)		
Net revenue . . . . .	\$404,241	\$348,157	\$257,534
Operating expenses:			
Cost of revenue . . . . .	118,148	88,355	66,502
Research and development . . . . .	117,610	105,720	77,255
Selling, general and administrative . . . . .	193,832	164,903	141,807
Total operating expenses . . . . .	<u>429,590</u>	<u>358,978</u>	<u>285,564</u>
Loss from operations . . . . .	(25,349)	(10,821)	(28,030)
Other (loss) income . . . . .	<u>(2,818)</u>	<u>5,235</u>	<u>10,653</u>
Loss before income taxes . . . . .	(28,167)	(5,586)	(17,377)
Provision for income taxes . . . . .	<u>(48,062)</u>	<u>(2,918)</u>	<u>(895)</u>
Net loss . . . . .	<u>\$ (76,229)</u>	<u>\$ (8,504)</u>	<u>\$ (18,272)</u>
Basic loss per common share . . . . .	\$ (1.46)	\$ (0.16)	\$ (0.35)
Diluted loss per common share . . . . .	\$ (1.46)	\$ (0.16)	\$ (0.35)
Weighted average number of common shares outstanding:			
Shares used in computing basic loss per common share . . . . .	52,269	51,904	51,624
Shares used in computing diluted loss per common share . . . . .	52,269	51,904	51,624

See accompanying notes to consolidated financial statements.

**THE MEDICINES COMPANY**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
**For The Years Ended December 31, 2007, 2008 and 2009**

	<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Accumulated Comprehensive (Loss) Income</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>				
Balance at January 1, 2007 . . . . .	51,227	51	511,076	(241,172)	(4)	269,951
Employee stock purchases . . . . .	498	1	9,329			9,330
Issuance of restricted stock awards . . . . .	141					—
Non-cash stock compensation . . . . .			15,386			15,386
Tax effect of option exercises . . . . .			1,236			1,236
Net loss . . . . .				(18,272)		(18,272)
Currency translation adjustment . . . . .					72	72
Unrealized gain on available for sale securities (net of tax) . . . . .					193	193
Comprehensive loss . . . . .						(18,007)
<b>Balance at December 31, 2007 . . . . .</b>	<b><u>51,866</u></b>	<b><u>\$52</u></b>	<b><u>\$537,027</u></b>	<b><u>\$(259,444)</u></b>	<b><u>\$ 261</u></b>	<b><u>\$277,896</u></b>
Employee stock purchases . . . . .	321	—	5,541			5,541
Issuance of restricted stock awards . . . . .	93					—
Non-cash stock compensation . . . . .			22,798			22,798
Tax effect of option exercises . . . . .			(283)			(283)
Net loss . . . . .				(8,504)		(8,504)
Currency translation adjustment . . . . .					(52)	(52)
Unrealized gain on available for sale securities (net of tax) . . . . .					629	629
Comprehensive loss . . . . .						(7,927)
<b>Balance at December 31, 2008 . . . . .</b>	<b><u>52,280</u></b>	<b><u>\$52</u></b>	<b><u>\$565,083</u></b>	<b><u>\$(267,948)</u></b>	<b><u>\$ 838</u></b>	<b><u>\$298,025</u></b>
Employee stock purchases . . . . .	231	—	1,803			1,803
Issuance of restricted stock awards . . . . .	319	1				1
Non-cash stock compensation . . . . .			19,437			19,437
Tax effect of option exercises . . . . .			(1,645)			(1,645)
Net loss . . . . .				(76,229)		(76,229)
Currency translation adjustment . . . . .					(297)	(297)
Unrealized loss on available for sale securities (net of tax) . . . . .					(706)	(706)
Comprehensive loss . . . . .						(77,232)
<b>Balance at December 31, 2009 . . . . .</b>	<b><u>52,830</u></b>	<b><u>\$53</u></b>	<b><u>\$584,678</u></b>	<b><u>\$(344,177)</u></b>	<b><u>\$(165)</u></b>	<b><u>\$240,389</u></b>

See accompanying notes to consolidated financial statements.



**THE MEDICINES COMPANY**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Year Ended December 31,		
	2009	2008	2007
	(In thousands)		
Cash flows from operating activities:			
Net loss	\$ (76,229)	\$ (8,504)	\$ (18,272)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Depreciation and amortization	5,767	2,932	1,586
Acquired in-process research and development	—	21,373	—
Impairment of investment	5,000	—	—
Amortization of net premiums and discounts on available for sale securities	2,118	113	(1,093)
Unrealized foreign currency transaction losses, net	—	580	—
Non-cash stock compensation expense	19,437	22,798	15,386
Loss on disposal of fixed assets	—	33	33
Loss on available for sale securities	33	33	2
Deferred tax provision	47,737	1,520	—
Tax effect of option exercises	—	—	1,236
Adjustment to contingent purchase price (see Note 6)	486	—	—
Changes in operating assets and liabilities:			
Accrued interest receivable	414	262	(184)
Accounts receivable	3,182	(7,614)	(4,260)
Inventory	2,774	6,890	6,160
Prepaid expenses and other current assets	(1,713)	(1,236)	5,718
Other assets	—	—	(4,983)
Accounts payable	(7,851)	3,315	907
Accrued expenses	8,343	(18,945)	36,770
Deferred revenue	(8,519)	9,588	(2,814)
Other liabilities	(28)	4,939	(95)
Net cash provided by operating activities	951	38,077	36,097
Cash flows from investing activities:			
Purchases of available for sale securities	(133,700)	(161,822)	(148,954)
Maturities and sales of available for sale securities	161,646	161,505	137,541
Purchases of fixed assets	(342)	(19,395)	(1,571)
Proceeds from sale of fixed assets	—	—	9
Acquisition of intangible assets	—	(2,000)	(14,929)
Investment in pharmaceutical company	—	(5,000)	—
Acquisition of business, net of cash acquired	(37,168)	(23,534)	—
Increase in restricted cash	(1,652)	—	(5,000)
Net cash used in investing activities	(11,216)	(50,246)	(32,904)
Cash flows from financing activities:			
Proceeds from issuances of common stock, net	1,804	5,542	9,330
Net cash provided by financing activities	1,804	5,542	9,330
Effect of exchange rate changes on cash	(332)	(482)	74
(Decrease) increase in cash and cash equivalents	(8,793)	(7,109)	12,597
Cash and cash equivalents at beginning of period	81,018	88,127	75,530
Cash and cash equivalents at end of period	\$ 72,225	\$ 81,018	\$ 88,127
Supplemental disclosure of cash flow information:			
Interest paid	\$ —	\$ —	\$ —
Taxes paid	\$ 358	\$ 2,518	\$ 769
Supplemental disclosure of non-cash investing activities:			
Fixed asset additions included in current liabilities	\$ —	\$ 6,327	\$ 308

See accompanying notes to consolidated financial statements.

**THE MEDICINES COMPANY**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Nature of Business**

The Medicines Company (the Company) is a global pharmaceutical company focused on advancing the treatment of critical care patients through the delivery of innovative, cost-effective medicines to the worldwide hospital marketplace. The Company has two marketed products, Angiomax® (bivalirudin) and Cleviprex® (clevidipine butyrate) injectable emulsion, and a pipeline of critical care hospital products in development, including two late-stage development product candidates, cangrelor and oritavancin, two early stage development product candidates, CU2010 and ApoA-I Milano, and marketing rights in the United States and Canada to a ready-to-use formulation of Argatroban for which a new drug application (NDA) has been submitted to the U.S. Food and Drug Administration (FDA). The Company believes that Angiomax, Cleviprex and its products in development possess favorable attributes that competitive products do not provide, can satisfy unmet medical needs in the critical care hospital product market and offer, or, in the case of the Company's products in development, have the potential to offer, improved performance to hospital businesses.

**2. Significant Accounting Policies**

*Basis of Presentation*

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation. The Company has no unconsolidated subsidiaries or investments accounted for under the equity method.

*Use of Estimates*

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, costs, expenses and accumulated other comprehensive income/(loss) that are reported in the consolidated financial statements and accompanying disclosures. Actual results may be different.

*Risks and Uncertainties*

The Company is subject to risks common to companies in the pharmaceutical industry including, but not limited to, uncertainties related to commercialization of products, regulatory approvals, dependence on key products, dependence on key customers and suppliers, and protection of intellectual property rights.

*Concentrations of Credit Risk*

Financial instruments that potentially subject the Company to concentration of credit risk include cash, cash equivalents, available for sale securities and accounts receivable. The Company believes it minimizes its exposure to potential concentrations of credit risk by placing investments in high-quality financial instruments with high quality institutions. At December 31, 2009, approximately \$25.1 million of the Company's cash and cash equivalents was invested in a single fund, the Dreyfus Cash Management Money Market Fund, a no-load money market fund with Capital Advisors Group. At December 31, 2008, approximately \$32.4 million of the Company's cash and cash equivalents was invested in a single fund, the Dreyfus Treasury and Agency Money Market Fund, a no-load money market fund, with the Capital Advisors Group.

In March 2007, the Company began selling Angiomax in the United States to a sole source distributor, Integrated Commercialization Solutions, Inc. (ICS). The Company began selling Cleviprex to ICS in September 2008. ICS accounted for 96% of the Company's net revenue for each of 2009 and 2008. At December 31, 2009 and 2008, amounts due from ICS represented approximately \$33.8 million and \$32.4 million, or 94% and 90%, of gross accounts receivable, respectively. From January 2007 through March 2007, the Company sold Angiomax primarily to a limited number of domestic wholesalers with distribution centers located throughout the United States and to several international distributors. ICS and the Company's two domestic

**THE MEDICINES COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

wholesaler customers, AmerisourceBergen Drug Corporation and Cardinal Health, Inc., accounted for 82%, 7% and 7%, respectively, of the Company's net revenue for 2007. At December 31, 2007, amounts due from the sole source distributor and the Company's two domestic wholesaler customers to the Company represented approximately \$25.3 million, or 93%, of the Company's gross accounts receivable.

***Cash, Cash Equivalents and Available for Sale Securities***

The Company considers all highly liquid investments purchased with original maturities at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents included cash of \$24.7 million and \$46.9 million at December 31, 2009 and December 31, 2008, respectively. Cash and cash equivalents at December 31, 2009 and December 31, 2008 included investments of \$47.5 million and \$34.1 million, respectively, in money market funds and commercial paper with original maturities of less than three months. These investments are carried at cost, which approximates fair value. The Company measures all original maturities from the date the investment was originally purchased by the Company.

The Company considers securities with original maturities of greater than three months to be available for sale securities. Securities under this classification are recorded at fair market value and unrealized gains and losses are recorded as a separate component of stockholders' equity. The estimated fair value of the available for sale securities is determined based on quoted market prices or rates for similar instruments. In addition, the cost of debt securities in this category is adjusted for amortization of premium and accretion of discount to maturity. The Company evaluates securities with unrealized losses to determine whether such losses are other than temporary.

The Company held available for sale securities with fair value totaling \$104.0 million at December 31, 2009 and \$135.2 million at December 31, 2008. These available for sale securities included various United States government agency notes, corporate debt securities and asset backed securities. At December 31, 2009, approximately \$100.3 million of available for sale securities were due on demand or within one year. The remaining \$3.7 million were due within two years. At December 31, 2008, all of the Company's available for sale securities were due within one year.

Available for sale securities, including carrying value and estimated fair values, are summarized as follows:

	As of December 31, 2009				As of December 31, 2008			
	Cost	Fair Value	Carrying Value	Unrealized Gain	Cost	Fair Value	Carrying Value	Unrealized Gain
	(In thousands)							
U.S. government agency notes . . . . .	\$103,936	\$103,965	\$103,965	\$29	\$107,513	\$108,491	\$108,491	\$ 978
Corporate debt securities . .	\$ —	\$ —	\$ —	\$—	\$ 26,487	\$ 26,697	\$ 26,697	\$ 210
Total . . . . .	<u>\$103,936</u>	<u>\$103,965</u>	<u>\$103,965</u>	<u>\$29</u>	<u>\$134,000</u>	<u>\$135,188</u>	<u>\$135,188</u>	<u>\$1,188</u>

***Investments***

The Company accounts for its investment in a minority interest of a company over which it does not exercise significant influence on the cost method in accordance with the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 325-20, "Cost Method Investments" (ASC 325-20). Under the cost method, an investment is carried at cost until it is sold or there is evidence that changes in the business environment or other facts and circumstances suggest it may be other than temporarily impaired based on criteria outlined in ASC 325-20. These non-marketable securities have been classified as investments and included in other assets on the consolidated balance sheets.

## THE MEDICINES COMPANY

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### *Restricted Cash*

The Company had restricted cash of \$7.0 million at December 31, 2009 and \$5.0 million at December 31, 2008, which is included in restricted cash on the consolidated balance sheets. On October 11, 2007, the Company entered into a new lease for office space in Parsippany, New Jersey. The Company relocated its principal executive offices to the new space in the first quarter of 2009. Restricted cash of \$6.8 million and \$5.0 million at December 31, 2009 and December 31, 2008, respectively, collateralizes outstanding letters of credit associated with this lease. The funds are invested in certificates of deposit. The letter of credit permits draws by the landlord to cure defaults by the Company. The amount of the letter of credit is subject to reduction upon the achievement of certain regulatory and operational milestones relating to the Company's products. However, in no event will the amount of the letter of credit be reduced below approximately \$1.0 million. In addition, as a result of the acquisition of Targanta Therapeutics Corporation (Targanta) in 2009, the Company's had restricted cash of \$0.2 million in the form of a guaranteed investment certificate collateralizing an available credit facility.

#### *Revenue Recognition*

*Product Sales.* The Company distributes Angiomax and Cleviprex in the United States through a sole source distribution model. Under this model, the Company sells Angiomax and Cleviprex to its sole source distributor, ICS, which then sells Angiomax and Cleviprex to a limited number of national medical and pharmaceutical wholesalers with distribution centers located throughout the United States and in certain cases, directly to hospitals. The Company's agreement with ICS, which it initially entered into February 2007, provides that ICS will be the Company's exclusive distributor of Angiomax and Cleviprex in the United States. Under the terms of this fee-for-service agreement, ICS assumes all credit and inventory risks, is subject to the Company's standard return policy, places orders with the Company for sufficient quantities of Angiomax and Cleviprex to maintain an appropriate level of inventory based on the Company's customers' historical purchase volumes and has sole responsibility for determining the prices at which it sells Angiomax and Cleviprex, subject to specified limitations in the agreement. The agreement terminates on February 28, 2011, but will automatically renew for additional one-year periods unless either party gives notice at least 120 days prior to the automatic extension. The Company may also terminate the agreement at any time and for any reason upon prior written notice to ICS and payment of a termination fee of between \$100,000 and \$250,000.

Outside of the United States, the Company sells Angiomax either directly to hospitals or to wholesalers or international distributors, which then sell Angiomax to hospitals. The Company had deferred revenue of \$0.4 million as of December 31, 2009 and December 31, 2008 associated with sales of Angiomax to wholesalers outside of the United States. The Company recognizes revenue from such sales when hospitals purchase the product.

The Company does not recognize revenue from product sales until there is persuasive evidence of an arrangement, delivery has occurred, the price is fixed and determinable, the buyer is obligated to pay the Company, the obligation to pay is not contingent on resale of the product, the buyer has economic substance, apart from the Company, the Company has no obligation to bring about the sale of the product, the amount of returns can be reasonably estimated and collectability is reasonably assured.

The Company began selling Cleviprex in the United States in September 2008. Initial gross wholesaler orders of Cleviprex in the United States in the third quarter of 2008 totaled \$10.0 million. The Company recorded this amount as deferred revenue as the Company could not estimate certain adjustments to gross revenue, including returns. Under this deferred revenue model, the Company does not recognize revenue upon product shipment to ICS. Instead, upon product shipment, the Company invoices ICS, records deferred revenue at gross invoice sales price, classifies the cost basis of the product held by ICS as finished goods inventory held by others and includes such cost basis amount within prepaid expenses and other current assets on its consolidated balance sheets. The Company currently recognizes the deferred revenue when hospitals purchase

## THE MEDICINES COMPANY

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

product and will do so until such time that it has sufficient information to develop reasonable estimates of expected returns and other adjustments to gross revenue. When such estimates are developed, the Company expects to recognize Cleviprex revenue upon shipment to ICS in the same manner as it recognizes Angiomax revenue. During the third quarter of 2009, the Company reduced its contract price for Cleviprex which had the effect of reducing the deferred revenue by approximately \$4.0 million. In the fourth quarter of 2009, the Company announced a voluntary recall of 11 lots of Cleviprex, including any remaining unsold inventory associated with its initial wholesaler orders, which resulted in a reduction of deferred revenue of approximately \$2.0 million. In 2009, the Company recognized \$3.0 million of Cleviprex revenue related to purchases by hospitals.

The Company records allowances for chargebacks and other discounts or accruals for product returns, rebates and fee-for-service charges at the time of sale, and reports revenue net of such amounts. In determining the amounts of certain allowances and accruals, the Company must make significant judgments and estimates. For example, in determining these amounts, the Company estimates hospital demand, buying patterns by hospitals and group purchasing organizations from wholesalers and the levels of inventory held by wholesalers and by ICS. Making these determinations involves estimating whether trends in past wholesaler and hospital buying patterns will predict future product sales. The Company receives data periodically from ICS and wholesalers on inventory levels and levels of hospital purchases and the Company considers this data in determining the amounts of these allowances and accruals.

The nature of the Company's allowances and accruals requiring critical estimates, and the specific considerations it uses in estimating their amounts are as follows.

- *Product returns.* The Company's customers have the right to return any unopened product during the 18-month period beginning six months prior to the labeled expiration date and ending 12 months after the labeled expiration date. As a result, in calculating the accrual for product returns, the Company must estimate the likelihood that product sold might not be used within six months of expiration and analyze the likelihood that such product will be returned within 12 months after expiration. The Company considers all of these factors and adjusts the accrual periodically throughout each quarter to reflect actual experience. When customers return product, they are generally given credit against amounts owed. The amount credited is charged to the Company's product returns accrual.

In estimating the likelihood of product being returned, the Company relies on information from ICS and wholesalers regarding inventory levels, measured hospital demand as reported by third-party sources and internal sales data. The Company also considers the past buying patterns of ICS and wholesalers, the estimated remaining shelf life of product previously shipped, the expiration dates of product currently being shipped, price changes of competitive products and introductions of generic products.

At December 31, 2009 and December 31, 2008, the Company's accrual for product returns was \$3.8 million and \$1.0 million, respectively. Included within the accrual at December 31, 2009 was a reserve of \$1.3 million that the Company established related to the Cleviprex product recall which occurred in December 2009. Included within the accrual at December 31, 2008 was a reserve of \$0.8 million that the Company established for existing inventory at Nycomed Danmark ApS (Nycomed) that Nycomed had the right to return at any time. In July 2009, the Company reimbursed Nycomed \$0.8 million for the final amount of inventory held by Nycomed at December 31, 2008. A 10% change in the Company's accrual for product returns would have had an approximate \$0.4 million effect on the Company's reported net revenue for the year ended December 31, 2009.

- *Chargebacks and rebates.* Although the Company primarily sells products to ICS in the United States, the Company typically enters into agreements with hospitals, either directly or through group

## THE MEDICINES COMPANY

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

purchasing organizations acting on behalf of their hospital members, in connection with the hospitals' purchases of products.

Based on these agreements, most of the Company's hospital customers have the right to receive a discounted price for products and volume-based rebates on product purchases. In the case of discounted pricing, the Company typically provides a credit to ICS, or a chargeback, representing the difference between ICS's acquisition list price and the discounted price. In the case of the volume-based rebates, the Company typically pays the rebate directly to the hospitals.

As a result of these agreements, at the time of product shipment, the Company estimates the likelihood that product sold to ICS might be ultimately sold to a contracting hospital or group purchasing organization. The Company also estimates the contracting hospital's or group purchasing organization's volume of purchases.

The Company bases its estimates on industry data, hospital purchases and the historic chargeback data it receives from ICS, most of which ICS receives from wholesalers, which detail historic buying patterns and sales mix for particular hospitals and group purchasing organizations, and the applicable customer chargeback rates and rebate thresholds.

The Company's allowance for chargebacks was \$4.7 million and \$1.2 million at December 31, 2009 and December 31, 2008, respectively. A 10% change in the Company's allowance for chargebacks would have had an approximate \$0.5 million effect on the Company's reported net revenue for the year ended December 31, 2009. The Company's accrual for rebates was \$0.0 million at December 31, 2009 and \$0.4 million at December 31, 2008.

- *Fees-for-service.* The Company offers discounts to certain wholesalers and ICS based on contractually determined rates for certain services. The Company estimates its fee-for-service accruals and allowances based on historical sales, wholesaler and distributor inventory levels and the applicable discount rate. The Company's discounts are accrued at the time of the sale and are typically settled with the wholesalers or ICS within 60 days after the end of each respective quarter. The Company's fee-for-service accruals and allowances were \$3.1 million and \$2.0 million at December 31, 2009 and December 31, 2008, respectively. A 10% change in the Company's fee-for-service accruals and allowances would have had an approximate \$0.3 million effect on the Company's net revenue for the year ended December 31, 2009.

The Company has adjusted its allowances for chargebacks and accruals for product returns, rebates and fees-for-service in the past based on actual sales experience, and the Company will likely be required to make adjustments to these allowances and accruals in the future. The Company continually monitors its allowances and accruals and makes adjustments when the Company believes actual experience may differ from its estimates. The allowances included in the table below reflect these adjustments.

**THE MEDICINES COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

The following table provides a summary of activity with respect to the Company's sales allowances and accruals during 2009, 2008 and 2007 (amounts in thousands):

	<u>Returns</u>	<u>Chargebacks</u>	<u>Rebates</u>	<u>Fees-for-Service</u>
<b>Balance at January 1, 2007</b> . . . . .	\$ 401	\$ 328	\$ 834	\$ 1,774
Allowances for sales during 2007 . . . . .	113	4,386	4,546	4,507
Allowances for prior year sales . . . . .	60	99	25	—
Allowances for sales in Nycomed territory . . . . .	2,959	—	—	—
Actual credits issued for prior year's sales . . . . .	(459)	(427)	(849)	(929)
Actual credits issued for sales during 2007 . . . . .	<u>(14)</u>	<u>(3,789)</u>	<u>(2,894)</u>	<u>(3,695)</u>
<b>Balance at December 31, 2007</b> . . . . .	3,060	597	1,662	1,657
Allowances for sales during 2008 . . . . .	138	5,628	1,413	6,562
Allowances for prior year sales . . . . .	159	123	—	—
Allowances for sales in Nycomed territory . . . . .	—	—	—	—
Actual credits issued for prior year's sales . . . . .	(261)	(720)	(1,397)	(721)
Actual credits issued for prior year sales in Nycomed territory . . . . .	(2,121)	—	—	—
Actual credits issued for sales during 2008 . . . . .	<u>—</u>	<u>(4,442)</u>	<u>(1,247)</u>	<u>(5,542)</u>
<b>Balance at December 31, 2008</b> . . . . .	975	1,186	431	1,956
Allowances for sales during 2009 . . . . .	3,764	13,439	212	9,582
Allowances for prior year sales . . . . .	274	—	—	—
Actual credits issued for prior year's sales . . . . .	(1,249)	(1,174)	(275)	(1,670)
Actual credits issued for sales during 2009 . . . . .	<u>—</u>	<u>(8,787)</u>	<u>(357)</u>	<u>(6,743)</u>
<b>Balance at December 31, 2009</b> . . . . .	<u>\$ 3,764</u>	<u>\$ 4,664</u>	<u>\$ 11</u>	<u>\$ 3,125</u>

Included within the 2007 allowances above is the reserve of \$3.0 million that the Company recorded during the fourth quarter of 2007 for the existing inventory at Nycomed which the Company did not believe would be sold prior to the termination of the transitional distribution agreement and would be subject to purchase in accordance with the agreement. During 2008, the Company reduced the reserve by \$2.2 million as Nycomed sold a portion of the existing inventory during the year. Such amount is included within the 2008 allowances above. In 2009, the Company reimbursed Nycomed \$0.8 million for the final amount of inventory held by Nycomed at December 31, 2008.

*International Distributors.* Under the Company's agreements with its primary international distributors, the Company sells Angiomax to these distributors at a fixed price. The established price is typically determined once per year, prior to the first shipment of Angiomax to the distributor each year. The minimum selling price used in determining the price is 50% of the average net unit selling price.

Revenue from the sale of products during 2007 includes the amortization of milestone payments. These milestone payments are recorded as deferred revenue until contractual performance obligations have been satisfied, and they are typically recognized ratably over the term of these agreements. When the period of deferral cannot be specifically identified from the contract, the Company must estimate the period based upon other critical factors contained within the contract. The Company reviews these estimates at least annually, which could result in a change in the deferral period. In connection with the Nycomed transaction (described in note 7 of these notes to the consolidated financial statements), the Company wrote-off approximately \$2.7 million of deferred revenue during the third quarter of 2007, which amount represented the unamortized portion of deferred revenue related to milestone payments received from Nycomed in 2004 and 2002.

## THE MEDICINES COMPANY

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Revenue associated with sales to the Company's international distributors during 2009, 2008 and 2007 was \$4.4 million, \$6.6 million and \$0.1 million, respectively. During 2007, international net revenue was reduced by \$3.0 million, which represented a reserve for existing inventory at Nycomed because the Company did not believe that such inventory would be sold by Nycomed prior to the termination of the Company's transitional distribution agreement with Nycomed and because such inventory was subject to return. During 2008, the Company reduced the Nycomed inventory reserve by \$2.2 million as Nycomed sold a portion of its existing inventory during the year. Such amounts are included in the \$6.6 million of revenue associated with sales to the Company's international distributors during 2008. As a result, the Company reduced its reserve for existing inventory to \$0.8 million, which resulted in an increase in international net revenue. The Company reimbursed Nycomed \$0.8 million in July 2009 for the final amount of inventory held by Nycomed at December 31, 2008.

*Revenue from Collaborations.* Under the terms of the transitional distribution agreement with Nycomed, the Company was entitled to receive a specified percentage of Nycomed's net sales of Angiox to third parties. In the event the Angiox sold was purchased by Nycomed from the Company prior to July 1, 2007, the amount the Company is entitled to receive in connection with such sale was reduced by the amount previously paid by Nycomed to the Company for such product. Accordingly, revenue related to the transitional distribution agreement with Nycomed entered into in 2007, under which Nycomed provided product distribution services through the second half of 2008, was not recognized until the product was sold by Nycomed to a hospital customer. For the year ended December 31, 2008, the Company recorded \$3.8 million of net revenue from sales made by Nycomed of approximately \$8.2 million under the transitional distribution agreement. The Company recorded such amount as revenue from collaborations and included it in net revenue on the Company's consolidated statements of operations. Because the Company assumed control of the distribution of Angiox in all countries in the former Nycomed territory by December 31, 2008, the Company did not have any revenue from collaborations during the year ended December 31, 2009.

#### *Cost of Revenue*

Cost of revenue consists of expenses in connection with the manufacture of Angiomax and Cleviprex sold, royalty expenses under the Company's agreements with Biogen Idec, Inc. (Biogen Idec), Health Research Inc. (HRI) and AstraZeneca AB (AstraZeneca) and the logistics costs of selling Angiomax and Cleviprex, such as distribution, storage and handling.

#### *Advertising Costs*

The Company expenses advertising costs as incurred. Advertising costs were approximately \$2.1 million, \$5.5 million and \$4.2 million for the years ended December 31, 2009, 2008, and 2007, respectively.

#### *Inventory*

The Company records inventory upon the transfer of title from the Company's vendors. Inventory is stated at the lower of cost or market value and valued using first-in, first-out methodology. Angiomax and Cleviprex bulk substance is classified as raw materials and its costs are determined using acquisition costs from the Company's contract manufacturers. The Company records work-in-progress costs of filling, finishing and packaging against specific product batches. The Company obtains all of its Angiomax bulk drug substance from Lonza Braine, S.A. Under the terms of the Company's agreement with Lonza Braine, the Company provides forecasts of its annual needs for Angiomax bulk substance 18 months in advance. The Company also has a separate agreement with Ben Venue Laboratories, Inc. for the fill-finish of Angiomax drug product. The Company obtains all of its Cleviprex bulk drug substance from Johnson Matthey Pharma Services and also has a separate agreement with Hospira, Inc. for the fill-finish of Cleviprex drug product.



## THE MEDICINES COMPANY

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### *Fixed Assets*

Fixed assets are stated at cost. Depreciation is provided using the straight-line method based on estimated useful lives or, in the case of leasehold improvements, over the lesser of the useful lives or the lease terms.

#### *Recoverability of Long-Lived Assets*

The Company reviews the carrying value of goodwill and indefinite lived intangible assets annually and whenever indicators of impairment are present. The Company determines whether goodwill may be impaired by comparing the carrying value of its reporting unit to the fair value of its reporting unit determined using an income approach valuation. A reporting unit is defined as an operating segment or one level below an operating segment. Long-lived assets used in operations and amortizing intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that carrying amounts may not be recoverable. For long-lived assets to be held and used, the Company recognizes an impairment loss only if its carrying amount is not recoverable through its undiscounted cash flows and measures the impairment loss based on the difference between the carrying amount and the fair value. Based on the Company's analysis, there was no impairment of goodwill and indefinite lived intangible assets in connection with the annual impairment tests that were performed during 2009.

#### *Research and Development*

Research and development costs are expensed as incurred.

#### *Stock-Based Compensation*

The Company accounts for share-based compensation in accordance with ASC topic 718-10 (ASC 718-10), and recognizes expense using the accelerated expense attribution method. ASC 718-10 requires companies to recognize compensation expense in an amount equal to the fair value of all share-based awards granted to employees. The Company estimates the fair value of its options on the date of grant using the Black-Scholes closed-form option-pricing model.

Expected volatilities are based on historic volatility of the Company's common stock as well as implied volatilities of peer companies in the life science industry over a range of periods from 12 to 60 months and other factors. The Company uses historical data to estimate forfeiture rate. The expected term of options represents the period of time that options granted are expected to be outstanding. The Company has made a determination of expected term by analyzing employees' historical exercise experience and has made estimates of future exercises of unexercised options based on the midpoint between the vesting date and end of the contractual term. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant corresponding with the expected life of the options.

#### *Translation of Foreign Currencies*

The functional currencies of the Company's foreign subsidiaries are the local currencies: Euro, Swiss franc, and British pound sterling. The Company's assets and liabilities are translated using the current exchange rate as of the balance sheet date. Stockholders' equity is translated using historical rates at the balance sheet date. Expenses and items of income are translated using a weighted average exchange rate over the period ended on the balance sheet date. Adjustments resulting from the translation of the financial statements of the Company's foreign subsidiaries into U.S. dollars are excluded from the determination of net earnings (loss) and are accumulated in a separate component of stockholders' equity. Foreign exchange transaction gains and losses are included in the Company's results of operations.

**THE MEDICINES COMPANY**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

***Income Taxes***

The Company historically provided for income taxes in accordance with SFAS No. 109, "Accounting for Income Taxes" (SFAS No. 109) and FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109" (FIN 48) both of which were later superseded by the FASB Codification and included in ASC topic 740 (ASC 740).

In accordance with ASC 740, the Company uses a two-step approach for recognizing and measuring tax benefits taken or expected to be taken in a tax return and disclosures regarding uncertainties in income tax positions. The first step is recognition: the Company determines whether it is more likely than not that a tax position will be sustained upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position. In evaluating whether a tax position has met the more-likely-than-not recognition threshold, the Company presumed that the position will be examined by the appropriate taxing authority that has full knowledge of all relevant information. The second step is measurement: a tax position that meets the more-likely-than-not recognition threshold is measured to determine the amount of benefit to recognize in the financial statements. The tax position is measured at the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement. The Company reduced its deferred tax asset attributable to certain tax credits by approximately \$1.2 million in 2007 and \$0.2 million in 2008 to appropriately measure the amount of such deferred tax asset. No adjustment was made in 2009. These adjustments did not affect the net deferred tax asset because such asset was subject to a valuation allowance. The recognition of this tax benefit may impact the effective income tax rate if such tax benefit is more likely than not to be realized when such benefit is recognized. The Company does not anticipate a significant change in its unrecognized tax benefits in the next twelve months. The Company is no longer subject to federal, state or foreign income tax audits for tax years prior to 2004, however such taxing authorities can review any net operating losses utilized by the Company in years subsequent to 2004.

In accordance with ASC 740, deferred tax assets and liabilities are determined based on differences between financial reporting and income tax bases of assets and liabilities, as well as net operating loss carryforwards, and are measured using the enacted tax rates and laws in effect when the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance to reflect the uncertainty associated with ultimate realization.

The Company recognizes potential interest and penalties relating to income tax positions as a component of the provision for income taxes.

***Comprehensive Income (Loss)***

The Company reports comprehensive income (loss) and its components in accordance with the provisions of SFAS No. 130, "Reporting Comprehensive Income", which was later superseded by the FASB Codification and included in ASC topic 220-10 (ASC 220-10). Comprehensive income (loss) includes net income (loss), all changes in equity for cumulative translations adjustments resulting from the consolidation of foreign subsidiaries' financial statements and unrealized gain (loss) on available for sale securities.

***Recent Accounting Pronouncements***

Effective January 1, 2009, the Company adopted the revised authoritative guidance on business combinations which changed existing practice, in part, as follows: contingent consideration arrangements are now fair valued at the acquisition date and included on that basis in the purchase price consideration; transaction costs are now expensed as incurred, rather than capitalized as part of the purchase price; reversal of valuation allowances created in purchase accounting are now recorded through the income tax provision; and in order to accrue for a restructuring plan in purchase accounting, all authoritative guidance would have to be met at the

**THE MEDICINES COMPANY**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

acquisition date. The Company accounted for the Targanta acquisition under this revised authoritative guidance, see note 6 of the notes to our consolidated financial statements included in this report.

In April 2009, the FASB issued FASB Staff Position No. FAS 107-1 and APB 28-1, "Interim Disclosures about Fair Value of Financial Instruments," which was later superseded by the FASB Codification, and included in ASC topic 825 (ASC 825-10-65) which requires disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. This guidance is effective for interim reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. The Company adopted this accounting pronouncement as of and for the period ended June 30, 2009 and this adoption did not have a material impact on its financial statements.

In April 2009, the FASB issued FASB Staff Position No. FAS 115-2 and FAS 124-2, "Recognition and Presentation of Other-Than-Temporary Impairments," which was later superseded by the FASB Codification and included in ASC topic 320 (ASC 320-10-65), which amends the other-than-temporary impairment guidance in GAAP for debt securities to make the guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. This guidance is effective for interim and annual reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. The Company adopted this accounting pronouncement as of and for the period ended June 30, 2009 and it did not have a material impact on its financial statements.

In May 2009, the FASB issued Statement of Financial Accounting Standard (SFAS) No. 165, "Subsequent Events", which was later superseded by the FASB Codification and included in ASC topic 855-10 (ASC 855-10). ASC 855-10 is intended to establish general standards of accounting for, and disclosure of, events that occur after the balance sheet date but before financial statements are issued or are available to be issued. ASC 855-10 requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for selecting that date, including whether that date represents the date the financial statements were issued or were available to be issued. ASC 855-10 is effective for interim or annual financial periods ending after June 15, 2009. The Company adopted this accounting pronouncement as of and for the period ended June 30, 2009 and it did not have a material impact on its financial statements.

In June 2009, the FASB issued SFAS No. 167, "Amendments to FASB Interpretation No. 46(R)", which was later superseded by the FASB Codification and included in ASC topic 810-10 (ASC 810-10), which modifies how a company determines when an entity that is insufficiently capitalized or is not controlled through voting (or similar rights) should be consolidated. ASC 810-10 clarifies that the determination of whether a company is required to consolidate an entity is based on, among other things, an entity's purpose and design and a company's ability to direct the activities of the entity that most significantly impact the entity's economic performance. ASC 810-10 requires an ongoing reassessment of whether a company is the primary beneficiary of a variable interest entity. ASC 810-10 also requires additional disclosures about a company's involvement in variable interest entities and any significant changes in risk exposure due to that involvement. This guidance is effective for fiscal years beginning after November 15, 2009 and is effective for the Company on January 1, 2010. The Company does not expect that the adoption of ASC 810-10 will have a material impact on the Company's results of operations or financial position.

In June 2009, the FASB issued SFAS No. 168, The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles, a replacement of FASB Statement No. 162. This statement modifies the GAAP hierarchy by establishing only two levels of GAAP, authoritative and nonauthoritative accounting literature. Effective July 2009, the FASB Codification is considered the single source of authoritative U.S. accounting and reporting standards, except for additional authoritative rules and interpretive releases issued by the SEC. Nonauthoritative guidance and literature would include, among other things, FASB Concepts Statements, American Institute of Certified Public Accountants Issue Papers and

**THE MEDICINES COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

Technical Practice Aids and accounting textbooks. The FASB Codification was developed to organize GAAP pronouncements by topic so that users can more easily access authoritative accounting guidance. It is organized by topic, subtopic, section, and paragraph, each of which is identified by a numerical designation. This statement applied beginning in third quarter 2009. All accounting references have been updated, and therefore SFAS references have been replaced with ASC references.

In August 2009, the FASB issued the FASB Codification update No. 2009-05 “Fair Value Measurements and Disclosures” (ASU 2009-05). The update is to subtopic ASC 820-10, Fair Value Measurements and Disclosures-Overall, for the fair value measurement of liabilities. The purpose of this update is to reduce ambiguity in financial reporting when measuring fair value of liabilities. The guidance in the update was effective for the Company during the three months ending September 30, 2009 and did not have a material impact on its financial statements.

**3. Inventory**

The major classes of inventory were as follows:

<u>Inventory</u>	<u>2009</u>	<u>2008</u>
	(In thousands)	
Raw materials . . . . .	\$13,609	\$10,003
Work-in-progress . . . . .	8,646	10,334
Finished goods . . . . .	<u>3,581</u>	<u>7,892</u>
<b>Total</b> . . . . .	<u>\$25,836</u>	<u>\$28,229</u>

The Company reviews inventory, including inventory purchase commitments, for slow moving or obsolete amounts based on expected revenues. As of December 31, 2008, the Company had an inventory obsolescence reserve of \$0.5 million related to Cleviprex. As of December 31, 2009, the obsolescence reserve related to Cleviprex was reduced to zero. If annual revenues are less than expected, the Company may be required to make additional allowances for excess or obsolete inventory in the future.

**4. Fixed Assets**

Fixed assets consist of the following:

	<u>Estimated Life (Years)</u>	<u>December 31,</u>	
		<u>2009</u>	<u>2008</u>
		(In thousands)	
Furniture, fixtures and equipment . . . . .	3-7	\$ 12,680	\$ 7,689
Computer software . . . . .	3	2,622	3,174
Computer hardware . . . . .	3	3,549	1,629
Leasehold improvements . . . . .	5-15	<u>20,485</u>	<u>21,235</u>
		39,336	33,727
Less: Accumulated depreciation . . . . .		<u>(14,264)</u>	<u>(6,396)</u>
		<u>\$ 25,072</u>	<u>\$27,331</u>

Depreciation expense was approximately \$4.6 million, \$2.4 million and \$1.6 million for the years ended December 31, 2009, 2008 and 2007, respectively.

**THE MEDICINES COMPANY**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**5. Investment**

On July 2, 2008, the Company made a short term convertible loan of \$5.0 million to Eagle Pharmaceuticals, Inc. (Eagle). This loan converted into 2.7 million shares of convertible preferred stock in the third quarter of 2008. At December 31, 2008, the investment in Eagle totaled \$5.0 million. The \$5.0 million was classified as investments and is included in other assets on the Company's consolidated balance sheets. In September 2009, pursuant to the license agreement that the Company entered into with Eagle, the Company agreed to make an additional \$2.0 million investment in shares of convertible preferred stock of Eagle in the fourth quarter of 2009 and pay a \$5.0 million technology license fee which the Company recorded as research and development expense. In December 2009, the Company amended its agreement with Eagle under which it was released from its obligation to make the additional equity investment. In the fourth quarter of 2009, the Company determined that the original \$5.0 million investment in Eagle was impaired and as a result wrote off the investment at December 31, 2009. The Company holds less than 10% of the issued and outstanding shares of Eagle and does not have significant influence over the company. Accordingly, the Company has accounted for the investment under the cost method.

**6. Acquisitions**

**Targanta Therapeutics Corporation**

In February 2009, the Company acquired Targanta, a biopharmaceutical company focused on developing and commercializing innovative antibiotics to treat serious infections in the hospital and other institutional settings.

Under the terms of the Company's agreement with Targanta, it paid Targanta shareholders an aggregate of approximately \$42.0 million at closing, and agreed to pay contingent cash payments up to an additional \$90.4 million in the aggregate, as described below:

- Upon approval from the European Agency for the Evaluation of Medical Products (EMA) for a MAA for oritavancin for the treatment of ABSSSI on or before December 31, 2013, approximately \$15.8 million if such approval is granted between January 1, 2010 and June 30, 2010, or approximately \$10.5 million if such approval is granted between July 1, 2010 and December 31, 2013. As of March 1, 2010, the Company has not filed an application with the EMA for oritavancin for the treatment of ABSSSI.
- Upon final approval from the FDA for a new drug application, or NDA, for oritavancin for the treatment of ABSSSI (1) within 40 months after the date the first patient is enrolled in a Phase 3 clinical trial of ABSSSI that is initiated by the Company and (2) on or before December 31, 2013, approximately \$10.5 million in the aggregate.
- Upon final FDA approval for an NDA for the use of oritavancin for the treatment of ABSSSI administered by a single dose intravenous infusion (1) within 40 months after the date the first patient is enrolled in a Phase 3 clinical trial of ABSSSI that is initiated by the Company and (2) on or before December 31, 2013, approximately \$14.7 million in the aggregate. This payment may become payable simultaneously with the payment described in the previous bullet above.
- If aggregate net sales of oritavancin in four consecutive calendar quarters ending on or before December 31, 2021 reach or exceed \$400 million, approximately \$49.4 million in the aggregate.

The transaction costs were expensed as incurred, the value of acquired in-process research and development was capitalized as an indefinite lived intangible asset and contingent payments were recorded at their estimated fair value. In 2009, the Company incurred a total of \$4.3 million of cost related to its acquisition of Targanta, which was included in selling, general and administrative expenses. The results of Targanta's operations since the acquisition date have been included in the Company's consolidated financial statements.

**THE MEDICINES COMPANY**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

The purchase price of approximately \$64 million, which includes \$42 million of cash paid upon acquisition and \$23 million that represents the fair market value of the contingent purchase price on the date of acquisition, was allocated to the net tangible and intangible assets of Targanta based on their estimated fair values. Below is a summary which details the assets and liabilities acquired as a result of the acquisition:

	(In thousands)
Acquired assets:	
Cash and cash equivalents .....	\$ 4,815
Available for sale securities .....	397
Prepaid expenses & other current assets .....	2,177
Fixed assets, net. ....	1,960
In-process research and development .....	69,500
Goodwill .....	14,934
Other assets .....	<u>70</u>
Total assets. ....	93,853
Liabilities assumed:	
Accounts payable .....	3,280
Accrued expenses. ....	6,976
Contingent purchase price .....	23,181
Deferred tax liability .....	17,877
Other liabilities .....	<u>556</u>
Total liabilities .....	<u>51,870</u>
Total cash purchase price paid upon acquisition .....	<u>\$41,983</u>

The purchase price was allocated to the estimated fair value of assets acquired and liabilities assumed based on a valuation and management estimates. The Company recorded a deferred tax liability for the difference in basis of the identifiable intangible assets.

In determining the fair value of all of the Company's in-process research and development projects related to oritavancin, the Company used the income approach, specifically a probability weighting to the estimated future net cash flows that are derived from projected sales revenues and estimated costs. These projections are based on factors such as relevant market size, patent protection, historical pricing of similar products and expected industry trends. This method requires a forecast of cash inflows, cash outflows, and pro forma charges for economic returns of and on tangible assets employed, including working capital, fixed assets and assembled workforce. Cash outflows include direct and indirect expenses for clinical trials, manufacturing, sales, marketing, general and administrative expenses and taxes. For purposes of these forecasts, the Company assumed that cash outflows for research and development, general administrative and marketing expenses from February 2009 and continuing through 2012 would not exceed \$165 million. All internal and external research and development expenses are expensed as incurred.

The Company expects the oritavancin development efforts to be material to its research and development expenses.

The Company defines an in-process research and development project by specific therapeutic treatment indication. At this time, the Company is pursuing four therapeutic treatment indications for oritavancin. After applying a risk adjusted discount rate of 13% to each project's expected cash flow stream, the Company determined a preliminary value for each project as set forth below. In determining these values, the Company

**THE MEDICINES COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

assumed that it would generate cash inflows from oritavancin for ABSSSI in 2012 and from the other projects thereafter.

Project	(In thousands)
ABSSSI . . . . .	\$54,000
Bacteremia . . . . .	5,900
Anthrax . . . . .	6,400
<i>Clostridium difficile</i> infections . . . . .	<u>3,200</u>
Total . . . . .	\$69,500

The Company’s success in developing and obtaining marketing approval for oritavancin for ABSSSI and for any of the other indications is highly uncertain. The Company has not finalized the design or the timing of the Phase 3 study of oritavancin required by the FDA. The Company cannot know or predict the nature, timing and estimated costs of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from, oritavancin due to the numerous risks and uncertainties associated with developing and commercializing drugs. These risks and uncertainties, including their impact on the timing of completing clinical trial and development work and obtaining regulatory approval, would have a material impact on each project’s value.

If the acquisition of Targanta had occurred as of January 1, 2008, the Company’s pro forma results for the years ended December 31, 2009 and 2008 would have been as follows:

	Years Ended December 31,	
	2009	2008
	(In thousands, except per share amounts)	
Net revenue . . . . .	\$404,241	\$348,157
Income (loss) from operations . . . . .	(36,020)	(70,219)
Net income (loss) . . . . .	(87,346)	(67,317)
Basic and diluted loss per share:		
Basic earnings (loss) per share . . . . .	\$ (1.67)	\$ (1.30)
Diluted earnings (loss) per share . . . . .	\$ (1.67)	\$ (1.30)
Weighted average number of common shares outstanding:		
Basic . . . . .	52,269	51,904
Diluted . . . . .	52,269	51,904

The above pro forma information was determined based on historical GAAP results adjusted for the elimination of interest foregone on net cash and cash equivalents used to pay the closing consideration and transaction related costs. Such amount was offset by the elimination of interest expense on third party debt that is assumed to be repaid in full prior to the completion of the acquisition.

**Curacyte Discovery GmbH**

In August 2008, the Company acquired Curacyte Discovery GmbH (Curacyte Discovery), a wholly owned subsidiary of Curacyte AG. Curacyte Discovery, a German limited liability company, was primarily engaged in the discovery and development of small molecule serine protease inhibitors. Its lead compound, CU2010, is being developed for the prevention of blood loss during surgery. In connection with the acquisition, the Company paid Curacyte AG an initial payment of €14.5 million (approximately \$22.9 million at the time of payment), €3.5 million in December 2009 and agreed to pay contingent milestone payments of up

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

to €32.0 million if the Company proceeds with further clinical development of CU2010 and achieves a commercial milestone. In addition, the Company agreed to pay royalties based on net sales.

The total cost of the acquisition was approximately \$23.7 million which included a purchase price of approximately \$22.9 million and direct acquisition costs of \$0.8 million. The results of Curacyte Discovery's operations since the acquisition date have been included in the Company's consolidated financial statements. Below is a summary which details the assets and liabilities acquired as a result of the acquisition:

	(In thousands)
<i>Acquired Assets:</i>	
Total current assets . . . . .	\$ 1,970
Fixed assets . . . . .	1,273
Other assets . . . . .	51
In-process research and development . . . . .	<u>21,373</u>
Total acquired assets . . . . .	24,667
<i>Acquired Liabilities:</i>	
Total current liabilities . . . . .	<u>(1,004)</u>
Total purchase price . . . . .	<u>\$23,663</u>

The purchase price was allocated to the estimated fair value of assets acquired and liabilities assumed based on a preliminary valuation and management estimates. The Company allocated approximately \$21.4 million of the purchase price to in-process research and development and was expensed upon completion of the acquisition. This amount was recorded as research and development in the consolidated statements of operations. The Company expects to finalize the purchase price allocation within one year from the date of the acquisition, pending final valuation.

**7. Nycomed Agreements**

On July 1, 2007, the Company entered into a series of agreements with Nycomed (collectively, the Agreements) pursuant to which the Company terminated its prior distribution agreement with Nycomed and reacquired all rights to develop, distribute and market the Company's product Angiox in the European Union (excluding Spain, Portugal and Greece, which territories are covered by another third-party distributor) and the former Soviet republics (the Nycomed Territory). Prior to entering into the Agreements, Nycomed served as the exclusive distributor of Angiox in the Nycomed Territory pursuant to a sales, marketing and distribution agreement, dated March 25, 2002, as amended.

Pursuant to the Agreements, the Company and Nycomed agreed to transition to the Company the Angiox rights held by Nycomed. Under these arrangements, the Company assumed control of the marketing of Angiox immediately and Nycomed agreed to provide, on a transitional basis, sales operations services, which ended December 31, 2007, and product distribution services through 2008. The Company assumed control of the distribution of Angiox in the majority of countries in the Nycomed Territory during the third quarter of 2008 and assumed control of the distribution in the remaining countries in the Nycomed Territory by December 31, 2008.

Under the terms of the transitional distribution agreement with Nycomed, upon the sale by Nycomed to third parties of vials of Angiox purchased by Nycomed from the Company prior to July 1, 2007 (the existing inventory), Nycomed was required to pay the Company a specified percentage of Nycomed's net sales of Angiox, less the amount previously paid by Nycomed to the Company for the existing inventory. In addition, under the transitional distribution agreement, Nycomed had the right to return any existing inventory for the price paid by Nycomed to the Company for such inventory. Included within the Company's accrual for product



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### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

return is a reserve of \$0.8 million and \$3.0 million, at December 31, 2008 and December 31, 2007, respectively, for existing inventory at Nycomed that Nycomed has the right to return at any time. During 2008, the Company reduced the reserve by \$2.2 million as Nycomed sold a portion of its existing inventory during the year. In July 2009, the Company reimbursed Nycomed \$0.8 million for the final amount of inventory held by Nycomed at December 31, 2008. The transitional distribution agreement terminated on December 31, 2008.

Under the transitional services agreement the Company had entered into with Nycomed, Nycomed agreed to perform detailing and other selling, sales management, product/marketing management, medical advisor, international marketing and certain pharmacovigilance services in accordance with an agreed upon marketing plan through December 31, 2007. The Company agreed to pay Nycomed's personnel costs, plus an agreed upon markup, for the performance of the services, in accordance with a budget detailed by country and function. In addition, the Company has agreed to pay Nycomed's costs, in accordance with a specified budget, for performing specified promotional activities during the term of the services agreement. These amounts were included in selling, general and administrative expense on the consolidated statements of operations as the Company received an identifiable benefit from these services and could reasonably estimate their fair value. For the year ended December 31, 2007, the Company recorded \$7.8 million of costs related to the services agreement with Nycomed. This agreement terminated on December 31, 2007.

The Company incurred total costs of \$45.7 million in connection with the reacquisition of the rights to develop, distribute and market Angiox in the Nycomed Territory. This total costs amount includes transaction fees of approximately \$0.7 million and agreed upon milestone payments of \$20.0 million paid to Nycomed on June 2, 2007, \$15.0 million paid to Nycomed on January 15, 2008 and \$5.0 million paid to Nycomed on July 8, 2008, as well as an additional \$5.0 million paid to Nycomed on July 8, 2008 in connection with the Company's obtaining European Commission approval to market Angiox for ACS in January 2008.

In the third quarter of 2007, the Company recorded approximately \$30.8 million as expense attributable to the termination of the prior distribution agreement with Nycomed. The \$30.8 million expense was offset in part by the write-off of approximately \$2.7 million of deferred revenue, which amount represented the unamortized portion of deferred revenue related to milestone payments received from Nycomed in 2004 and 2002. Such amounts were included in selling, general and administrative expense on the consolidated statements of operations for the year ended December 31, 2007. The Company allocated to intangible assets approximately \$14.9 million of the costs associated with the reacquisition of the rights to develop, distribute and market Angiox in the European Union. The Company is amortizing these intangible assets over the remaining patent life of Angiox, which expires in 2015. The period in which amortization expense will be recorded reflects the pattern in which the Company expects the economic benefits of the intangible assets to be consumed.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**8. Intangible Assets and Goodwill**

The following information details the carrying amounts and accumulated amortization of the Company's intangible assets subject to amortization:

	Weighted Average Useful Life	As of December 31, 2009			As of December 31, 2008		
		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
(In thousands)							
Identifiable intangible assets							
Customer relationships(1) . .	8 years	\$ 7,457	\$ (861)	\$ 6,596	\$ 7,457	\$(288)	\$ 7,169
Distribution agreement(1) . .	8 years	4,448	(514)	3,934	4,448	(171)	4,277
Trademarks(1) . . . . .	8 years	3,024	(349)	2,675	3,024	(116)	2,908
Cleviprex milestones(2) . . .	13 years	2,000	(27)	1,973	2,000	(5)	1,995
<b>Total</b> . . . . .	<u>9 years</u>	<u>\$16,929</u>	<u>\$(1,751)</u>	<u>\$15,178</u>	<u>\$16,929</u>	<u>\$(580)</u>	<u>\$16,349</u>

- (1) The Company amortizes intangible assets related to Angiox based on the ratio of annual forecasted revenue compared to total forecasted revenue from the sale of Angiox through the end of its patent life.
- (2) The Company amortizes intangible assets related to the Cleviprex approval over the remaining life of the patent.

The Company recorded \$2.0 million of intangible assets during the third quarter of 2008 in connection with payments required to be made upon the FDA's approval of Cleviprex for the reduction of blood pressure when oral therapy is not feasible or not desirable which occurred on August 1, 2008. As a result of such approval, the Company paid a \$1.5 million milestone payment to AstraZeneca under the terms of the Company's patent license agreement with AstraZeneca and a \$0.5 million payment to Hospira for development work under the Company's manufacturing agreement with Hospira. The Company is amortizing intangible assets related to the Cleviprex approval over the remaining life of the patent.

Amortization expense was approximately \$1.2 million and \$0.6 million for year ended December 31, 2009 and December 31, 2008, respectively. The Company did not record amortization expense in 2007 as it believed that the economic benefits received from the intangible assets did not begin until 2008. The Company expects annual amortization expense related to these intangible assets to be \$1.8 million, \$2.4 million, \$2.4 million, \$3.0 million and \$3.6 million for the years ending December 31, 2010, 2011, 2012, 2013 and 2014, respectively, with the balance of \$2.0 million being amortized thereafter. Amortization of customer relationships, distribution agreements and trademarks will be recorded in selling, general and administrative expense on the consolidated statements of operations. Amortization of Cleviprex milestones will be recorded in cost of revenue on the consolidated statements of operations.

**THE MEDICINES COMPANY**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

The following information details the carrying amounts of the Company's intangible assets not subject to amortization:

	As of December 31, 2009			As of December 31, 2008		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
	(In thousands)					
Intangible assets not subject to amortization:						
In-process research and development .....	\$69,500	\$—	\$69,500	\$—	\$—	\$—
<b>Total</b> .....	<u>\$69,500</u>	<u>\$—</u>	<u>\$69,500</u>	<u>\$—</u>	<u>\$—</u>	<u>\$—</u>

The changes in goodwill for the years ended December 31, 2009 and December 31, 2008 are as follows:

	December 31, 2009	December 31, 2008
		(In thousands)
Balance at beginning of period .....	\$ —	\$—
Goodwill acquired during the year .....	14,934	—
Balance at end of period .....	<u>\$14,934</u>	<u>\$—</u>

The goodwill acquired during 2009 is solely attributable to the Targanta acquisition (Note 6).

**9. Accrued Expenses**

Accrued expenses consisted of the following at December 31:

	2009	2008
		(In thousands)
Nycomed service agreement .....	\$ 71	\$ 2,385
Royalties .....	20,523	15,792
Research and development services .....	15,208	13,312
Compensation related .....	14,638	8,889
Product returns, rebates and other fees .....	5,992	3,286
Fixed asset additions .....	—	6,165
Legal, accounting and other .....	7,598	4,172
Manufacturing, logistics and related fees .....	10,332	4,929
Sales and marketing .....	<u>2,726</u>	<u>2,098</u>
	<u>\$77,088</u>	<u>\$61,028</u>

**10. Stockholders' Equity**

*Preferred Stock*

The Company has 5,000,000 shares of preferred stock (Preferred Stock) authorized, none of which are issued.

**THE MEDICINES COMPANY**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

*Common Stock*

Common stockholders are entitled to one vote per share and dividends when declared by the Company's Board of Directors, subject to the preferential rights of any outstanding shares of Preferred Stock.

Employees and directors of the Company purchased 231,022 shares, 320,638 shares, and 497,885 shares of common stock during the years ended December 31, 2009, 2008 and 2007, respectively, pursuant to option exercises and the Company's employee stock purchase plan. The aggregate net proceeds to the Company resulting from these purchases were approximately \$1.8 million, \$5.5 million, and \$9.3 million during the years ended December 31, 2009, 2008 and 2007, respectively, and are included within the financing activities section of the consolidated statements of cash flows. The Company issued 319,348 shares, 92,970 shares and 141,200 shares under restricted stock awards during the year ended December 31, 2009, 2008 and 2007, respectively.

**11. Stock-Based Compensation**

*Stock Plans*

The Company has adopted the following stock incentive plans:

- the 2009 Equity Inducement Plan (the 2009 Plan),
- the 2007 Equity Inducement Plan (the 2007 Plan),
- the 2004 Stock Incentive Plan (the 2004 Plan),
- the 2001 Non-Officer, Non-Director Stock Incentive Plan (the 2001 Plan),
- the 2000 Outside Director Stock Option Plan (the 2000 Director Plan), and
- the 1998 Stock Incentive Plan (the 1998 Plan).

Each of these plans provides for the grant of stock options and other stock-based awards to employees, officers, directors, consultants and advisors of the Company and its subsidiaries. Stock option grants have an exercise price equal to the fair market value of the Company's common stock on the date of grant and generally have a 10-year term. The fair value of stock option grants is recognized, net of an estimated forfeiture rate, using an accelerated method over the vesting period of the options, which is generally four years.

*2009 Plan*

In February 2009, the Board of Directors adopted the 2009 Plan, which provides for the grant of stock options, restricted stock awards, stock appreciation rights and other stock-based awards to any person who (a) was not previously an employee or director of the Company or (b) is commencing employment with the Company following a bona fide period of non-employment by the Company, as an inducement material to the individual entering into employment with the Company. The purpose of the 2009 Plan is to advance the interests of the Company's stockholders by enhancing the Company's ability to attract, retain and motivate persons who are expected to make important contributions to the Company and providing such persons with equity ownership opportunities that are intended to better align their interests with those of the Company's stockholders. The 2009 Plan is administered by the Compensation Committee of the Board of Directors, which had the authority to grant awards under the 2009 Plan. Under the 2009 Plan, the Company is authorized to issue up to 1,500,000 shares of common stock, subject to adjustment in the event of stock splits and other similar events, pursuant to awards granted under the 2009 Plan. Options granted under the 2009 Plan generally have a 10-year term and vest 25% one year after grant and the remaining options vest in equal monthly

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

installments over a three-year period. As of December 31, 2009, an aggregate of 359,800 options were issued and remained outstanding under the 2009 Plan.

*2007 Plan*

In December 2007, the Board of Directors adopted the 2007 Plan, which provided for the grant of stock options, restricted stock awards, stock appreciation rights and other stock-based awards to any person who (a) was not previously an employee or director of the Company or (b) is commencing employment with the Company following a bona fide period of non-employment by the Company, as an inducement material to the individual entering into employment with the Company. The purpose of the 2007 Plan was to advance the interests of the Company's stockholders by enhancing the Company's ability to attract, retain and motivate persons who were expected to make important contributions to the Company and providing such persons with equity ownership opportunities that were intended to better align their interests with those of the Company's stockholders. The 2007 Plan was administered by the Compensation Committee of the Board of Directors, which had the authority to grant awards under the 2007 Plan. Under the 2007 Plan, the Company was authorized to issue up to 1,700,000 shares of common stock, subject to adjustment in the event of stock splits and other similar events, pursuant to awards granted under the 2007 Plan. Options granted under the 2007 Plan generally had a 10-year term and vest 25% one year after grant and the remaining options vest in equal monthly installments over a three-year period. The 2007 Plan terminated on May 29, 2008. As of December 31, 2009, an aggregate of 525,651 options had been issued and remained outstanding under the 2007 Plan.

*2004 Plan*

In April 2004, the Board of Directors adopted, subject to stockholder approval, the 2004 Plan, which provides for the grant of stock options, restricted stock awards, stock appreciation rights and other stock-based awards to the Company's employees, officers, directors, consultants and advisors, including any individuals who have accepted an offer of employment. The Company's stockholders approved the 2004 Plan in May 2004. The 2004 Plan has been amended twice to increase the number of shares issuable under the 2004 Plan and to replace the existing sublimit on certain types of awards that may be granted under the 2004 Plan with a fungible share pool.

The Company may issue up to 11,800,000 shares of common stock, subject to adjustment in the event of stock splits and other similar events, pursuant to awards granted under the 2004 Plan. Shares awarded under the 2004 Plan that are subsequently cancelled are available to be granted again under the 2004 Plan. The Board of Directors has delegated its authority under the 2004 Plan to the Compensation Committee, consisting of independent directors, which administers the 2004 Plan, including granting options and other awards under the 2004 Plan. In addition, pursuant to the terms of the 2004 Plan, the Board of Directors has delegated to the Company's executive officers limited authority to grant stock options to employees without further action by the Board of Directors or the Compensation Committee. Options granted under the 2004 Plan generally have a 10-year term and commence vesting one year after grant and vest in equal monthly installments over a three-year period.

The Board of Directors has adopted a program under the 2004 Plan providing for automatic grants of options to the Company's non-employee directors. Each non-employee director is granted non-statutory stock options under the 2004 Plan to purchase:

- 20,000 shares of common stock on the date of his or her initial election to the Board of Directors (the Initial Options); and
- 7,500 shares of the common stock on the date of each annual meeting of the Company's stockholders (the Annual Options), except if such non-employee director was initially elected to the Board of

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### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Directors at such annual meeting. The lead director will be granted an additional option to purchase 5,000 shares of the common stock on the date of each annual meeting of the Company's stockholders.

Each non-employee director also receives an award of 3,750 shares of restricted stock on the date of each annual meeting of the Company's stockholders.

These options have an exercise price equal to the closing price of the common stock on the NASDAQ Global Select Market on the date of grant and have a 10-year term. The Initial Options vest in 36 equal monthly installments beginning on the date one month after the grant date. The Annual Options vest in 12 equal monthly installments beginning on the date one month after the date of grant. All vested options are exercisable at any time prior to the first anniversary of the date the director ceases to be a director. The restricted stock awards vest on the first anniversary date after the grant date.

As of December 31, 2009, the Company had granted an aggregate of 9,614,296 shares as restricted stock or subject to issuance upon exercise of stock options under the 2004 Plan, of which 8,366,419 shares remained subject to outstanding options.

#### *2001 Plan*

In May 2001, the Board of Directors approved the 2001 Plan, which provides for the grant of non-statutory stock options to employees, consultants and advisors of the Company and its subsidiaries, including individuals who have accepted an offer of employment, other than those employees who are officers or directors of the Company. The 2001 Plan provides for the issuance of up to 1,250,000 shares of common stock. Shares awarded under the 2001 Plan that were subsequently cancelled were available to be granted again under the 2001 Plan. The Board of Directors delegated its authority under the 2001 Plan to the Compensation Committee, which administers the 2001 Plan, including granting options under the 2001 Plan. In addition, pursuant to the terms of the 2001 Plan, the Board of Directors delegated to the Company's chief executive officer limited authority to grant stock options to employees without further action by the Board of Directors or the Compensation Committee. The Company ceased making grants under the 2001 Plan following adoption of an amendment to the 2004 Plan at the Company's annual stockholders' meeting on May 25, 2006.

As of December 31, 2009, an aggregate of 1,124,277 shares had been issued under the 2001 Plan and options to purchase an aggregate of 219,501 shares remained outstanding.

#### *2000 Director Plan*

Prior to the adoption of the 2004 Plan, the Company granted non-statutory stock options to the Company's non-employee directors pursuant to the 2000 Director Plan. The Company ceased making grants under the 2000 Director Plan following adoption of the 2004 Plan.

As of December 31, 2009, an aggregate of 204,586 shares had been issued under the 2000 Directors Plan and options to purchase an aggregate of 134,167 shares remained outstanding.

#### *1998 Plan*

In April 1998, the Company adopted the 1998 Plan, which provided for the grant of stock options, restricted stock and other stock-based awards to employees, officers, directors, consultants, and advisors of the Company and its subsidiaries, including any individuals who have accepted an offer of employment. The 1998 Plan terminated in April 2008. Under the 1998 Plan, the Board of Directors had authority to determine the term of each option, the option price, the number of shares for which each option is granted and the rate at which each option becomes exercisable. The 1998 Plan provided that 6,118,259 shares of common stock could be issued pursuant to awards under the 1998 Plan. Shares awarded under the 1998 Plan that were subsequently cancelled were available to be granted again under the 1998 Plan. During 1999, the Board of Directors

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

amended all then-outstanding options to allow holders to exercise the options prior to vesting, provided that the shares of common stock issued upon exercise of the option would be subject to transfer restrictions and vesting provisions that allowed the Company to repurchase unvested shares at the exercise price. There were no outstanding unvested shares of common stock under the 1998 Plan at December 31, 2009 and 2008. The Board of Directors delegated its authority under the 1998 Plan to the Compensation Committee, which administered the 1998 Plan, including granting options and other awards under the 1998 Plan. In addition, pursuant to the terms of the 1998 Plan, the Board of Directors delegated to the Company's chief executive officer limited authority to grant stock options to employees without further action by the Board of Directors or the Compensation Committee. Options granted under the 1998 Plan generally vest in increments over four years and have a ten-year term. The Company ceased making grants under the 1998 Plan following adoption of an amendment to the 2004 Plan at its annual stockholders' meeting on May 25, 2006.

As of December 31, 2009, an aggregate of 5,402,479 shares had been issued under the 1998 Plan and of such issuances, options to purchase an aggregate of 1,381,679 shares remained outstanding.

*Stock Option Activity*

The following table presents a summary of option activity and data under the Company's stock incentive plans as of December 31, 2009:

	<u>Number of Shares</u>	<u>Weighted-Average Exercise Price Per Share</u>	<u>Weighted- Average Remaining Contractual Term</u>	<u>Aggregate Intrinsic Value</u>
Outstanding, January 1, 2007 . . . . .	6,753,407	21.21		
Granted . . . . .	1,975,189	23.69		
Exercised . . . . .	(418,126)	19.14		
Forfeited and expired . . . . .	<u>(387,316)</u>	<u>23.43</u>		
Outstanding, December 31, 2007 . . . . .	7,923,154	21.83		
Granted . . . . .	3,588,990	19.25		
Exercised . . . . .	(217,160)	18.36		
Forfeited and expired . . . . .	<u>(538,373)</u>	<u>24.16</u>		
Outstanding, December 31, 2008 . . . . .	10,756,611	\$20.92		
Granted . . . . .	1,533,850	10.92		
Exercised . . . . .	(18,505)	5.85		
Forfeited and expired . . . . .	<u>(1,284,739)</u>	<u>20.23</u>		
Outstanding, December 31, 2009 . . . . .	10,987,217	\$19.63	5.58	\$1,259,632
Exercisable, December 31, 2009 . . . . .	7,453,320	\$21.00	4.67	\$1,070,869
Available for future grant at December 31, 2009 . . . . .	3,117,328			

Aggregate intrinsic value is the sum of the amounts by which the quoted market price of the Company's common stock exceeded the exercise price of the options at December 31, 2009, for those options for which the quoted market price was in excess of the exercise price. The weighted-average grant date fair value of options granted during the years ended December 31, 2009, 2008 and 2007 was \$4.69, \$8.08, and \$11.17, respectively. The total intrinsic value of options exercised during the years ended December 31, 2009, 2008 and 2007 was \$0.1 million, \$1.2 million, and \$4.3 million, respectively.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

In accordance with ASC 718-10, the Company recorded approximately \$19.4 million, \$20.2 million and \$13.5 million of stock compensation expense for the years ended December 31, 2009, 2008 and 2007, respectively. As of December 31, 2009, there was approximately \$13.0 million of total unrecognized compensation costs related to non-vested share-based employee compensation arrangements granted under the Company's equity compensation plans. This cost is expected to be recognized over a weighted average period of 1.22 years.

For purposes of performing the valuation, employees were separated into two groups according to patterns of historical exercise behavior; the weighted average assumptions below include assumptions from the two groups of employees exhibiting different behavior.

The Company estimated the fair value of each option on the date of grant using the Black-Scholes closed-form option-pricing model applying the weighted average assumptions in the following table.

	<b>Years Ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
Expected dividend yield . . . . .	0%	0%	0%
Expected stock price volatility . . . . .	47%	45%	49%
Risk-free interest rate . . . . .	2.05%	2.78%	4.49%
Expected option term (years) . . . . .	5.12	4.89	4.85

The fair value of each option element of the Company's 2000 Employee Stock Purchase Plan (the 2000 ESPP) is estimated on the date of grant using the Black-Scholes closed-form option-pricing model applying the weighted average assumptions in the following table. Expected volatilities are based on historical volatility of the Company's common stock. Expected term represents the six-month offering period for the 2000 ESPP. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant.

	<b>Years Ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
Expected dividend yield . . . . .	0%	0%	0%
Expected stock price volatility . . . . .	79%	39%	33%
Risk-free interest rate . . . . .	0.32%	2.04%	5.08%
Expected option term (years) . . . . .	0.5	0.5	0.5



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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

The following table summarizes information regarding options outstanding as of December 31, 2009:

Range of Exercise Prices Per Share	Options Outstanding			Options Vested	
	Number Outstanding at 12/31/09	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price Per Share	Number Outstanding at 12/31/09	Weighted Average Exercise Price Per Share
\$1.23 — \$15.50 . . . . .	2,008,759	5.82	\$10.04	807,595	\$ 9.71
\$15.59 — \$17.98 . . . . .	851,715	7.22	17.07	388,417	17.12
\$18.00 — \$18.27 . . . . .	927,158	4.06	18.26	893,638	18.26
\$18.29 — \$19.06 . . . . .	1,031,839	6.21	18.69	689,545	18.67
\$19.09 — \$19.89 . . . . .	1,850,346	6.58	19.41	987,166	19.71
\$19.98 — \$23.79 . . . . .	1,692,969	5.55	21.57	1,365,410	21.71
\$23.80 — \$28.01 . . . . .	1,299,038	3.58	26.16	1,180,722	26.23
\$28.02 — \$28.60 . . . . .	1,076,060	5.51	28.41	906,514	28.37
\$28.81 — \$34.95 . . . . .	249,333	4.66	31.32	234,313	31.40
	<u>10,987,217</u>	<u>5.58</u>	<u>\$19.63</u>	<u>7,453,320</u>	<u>\$21.00</u>

The following table presents a summary of the Company's outstanding shares of restricted stock awards granted as of December 31, 2009:

	Number of Shares	Weighted Average Grant-Date Fair Value
Outstanding, January 1, 2007 . . . . .	159,950	20.11
Awarded . . . . .	141,200	25.03
Vested . . . . .	(6,250)	20.11
Forfeited . . . . .	—	—
Outstanding, December 31, 2007 . . . . .	159,950	24.46
Awarded . . . . .	92,970	18.93
Vested . . . . .	(64,050)	22.65
Forfeited . . . . .	—	—
Outstanding, December 31, 2008 . . . . .	188,870	22.35
Awarded . . . . .	408,184	12.42
Vested . . . . .	(77,938)	21.56
Forfeited . . . . .	(88,836)	15.67
Outstanding, December 31, 2009 . . . . .	<u>430,280</u>	<u>\$14.45</u>

The Company grants restricted stock awards under the 2004 Plan. The restricted stock granted to employees generally vests in equal increments of 25% per year on an annual basis commencing twelve months after grant date. The restricted stock granted to non-employee directors generally vests on the first anniversary date after the grant date. Expense of approximately \$3.2 million, \$2.0 million and \$1.5 million was recognized in the years ended December 31, 2009, 2008 and 2007, respectively. The remaining expense of approximately \$2.8 million will be recognized over a period of 1.42 years. The total fair value of the restricted stock that vested during the years ended December 31, 2009, 2008 and 2007 was \$0.7 million, \$0.9 million and \$0.2 million, respectively.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

*2000 ESPP*

In May 2000, the Board of Directors and the Company's stockholders approved the 2000 ESPP, which provides for the issuance of up to 805,500 shares of common stock. The number of shares the Company may issue under the 2000 ESPP reflects an amendment approved by the Board of Directors on April 11, 2006 and by stockholders at the 2006 annual meeting. The 2000 ESPP permits eligible employees to purchase shares of common stock at the lower of 85% of the fair market value of the common stock at the beginning or at the end of each offering period. Employees who own 5% or more of the common stock are not eligible to participate in the 2000 ESPP. Participation is voluntary.

As of December 31, 2009, the Company had issued 636,196 shares over the life of the 2000 ESPP. The Company issued 212,517 shares, 103,478 shares, and 79,759 shares under the 2000 ESPP during the years ended December 31, 2009, 2008 and 2007, respectively, and currently has 169,304 shares in reserve for future issuance under the 2000 ESPP. The Company recorded approximately \$0.8 million, \$0.6 million, and \$0.4 million in compensation expense related to the 2000 ESPP in the years ended December 31, 2009, 2008 and 2007.

*Common Stock Reserved for Future Issuance*

At December 31, 2009, there were 169,304 shares of common stock available for grant under the 2000 ESPP, 1,978,128 shares of common stock available for grant under the 2004 Plan, and 1,140,200 shares of common stock available for grant under the 2009 Inducement Plan.

**12. Earnings (Loss) per Share**

The following table sets forth the computation of basic and diluted earnings (loss) per share for the years ended December 31, 2009, 2008 and 2007.

	<u>Years Ended December 31,</u>		
	<u>2009</u>	<u>2008</u>	<u>2007</u>
	<u>(In thousands, except per share amounts)</u>		
<b><i>Basic and diluted</i></b>			
Net loss . . . . .	\$(76,229)	\$(8,504)	\$(18,272)
Weighted average common shares outstanding, basic . . . . .	52,722	52,090	51,742
Less: unvested restricted common shares outstanding . . . . .	<u>453</u>	<u>186</u>	<u>118</u>
Net weighted average common shares outstanding, basic . . . . .	52,269	51,904	51,624
Plus: net effect of dilutive stock options and restricted common shares . . . . .	<u>—</u>	<u>—</u>	<u>—</u>
Weighted average common shares outstanding, diluted . . . . .	<u>52,269</u>	<u>51,904</u>	<u>51,624</u>
Loss per common share, basic . . . . .	\$ (1.46)	\$ (0.16)	\$ (0.35)
Loss per common share, diluted . . . . .	\$ (1.46)	\$ (0.16)	\$ (0.35)

Basic earnings (loss) per share is computed using the weighted average number of shares of common stock outstanding during the period, reduced where applicable for outstanding yet unvested shares of restricted common stock. The number of dilutive common stock equivalents was calculated using the treasury stock method. The table below provides details of the weighted average number of outstanding options and restricted

**THE MEDICINES COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

stock that were excluded in the calculation of diluted earnings per share for the year ended December 31, 2009, 2008 and 2007 as their effect would have been anti-dilutive.

	Years Ended December 31,		
	2009	2008	2007
	(In thousands)		
Weighted average options outstanding . . . . .	11,280	10,118	7,429
Weighted average options included in computation of diluted earnings per share . . . . .	—	—	—
Weighted average options considered anti-dilutive and excluded from the computation of diluted earnings per share . . . . .	<u>11,280</u>	<u>10,118</u>	<u>7,429</u>
Weighted average restricted shares outstanding . . . . .	453	186	118
Weighted average restricted shares included in computation of diluted earnings per share . . . . .	—	—	—
Weighted average restricted shares considered anti-dilutive and excluded from the computation of diluted earnings per share . . . . .	<u>453</u>	<u>186</u>	<u>118</u>

**13. Income Taxes**

The (provision for) benefit from income taxes in 2009, 2008 and 2007 consists of current and deferred federal, state and foreign taxes based on income and state taxes based on net worth as follows:

	2009	2008	2007
	(In thousands)		
Current:			
Federal . . . . .	\$ (237)	\$ (377)	\$(556)
State . . . . .	(238)	(1,021)	(339)
Foreign . . . . .	150	—	—
	<u>(325)</u>	<u>(1,398)</u>	<u>(895)</u>
Deferred:			
Federal . . . . .	(43,740)	(1,910)	—
State . . . . .	(3,997)	390	—
Foreign . . . . .	—	—	—
	<u>(47,737)</u>	<u>(1,520)</u>	<u>—</u>
Total (provision for)/benefit from income taxes . . . . .	<u>\$(48,062)</u>	<u>\$(2,918)</u>	<u>\$(895)</u>

The components of (loss) income before income taxes consisted of:

	2009	2008	2007
	(In thousands)		
Domestic . . . . .	\$(15,744)	\$ 7,489	\$(17,432)
International . . . . .	(12,423)	(13,075)	55
Total . . . . .	<u>\$(28,167)</u>	<u>\$ (5,586)</u>	<u>\$(17,377)</u>

**THE MEDICINES COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

The difference between tax expense and the amount computed by applying the statutory federal income tax rate of 35% in 2009, 2008, and 2007 to income before income taxes is as follows:

	<u>Year Ended December 31,</u>		
	<u>2009</u>	<u>2008</u>	<u>2007</u>
	(In thousands)		
Statutory rate applied to pre-tax loss . . . . .	\$(9,858)	\$(1,955)	\$(6,082)
Add (deduct):			
State income taxes, net of federal benefit . . . . .	2,753	430	240
Foreign . . . . .	168	4,576	(19)
Tax credits . . . . .	(1,408)	(1,456)	(1,106)
Lobbying costs . . . . .	1,701	219	1,121
Acquisition costs . . . . .	1,398	558	—
Meals and entertainment . . . . .	272	191	163
Tax reserves . . . . .	—	150	—
Other . . . . .	326	205	82
Increase (decrease) to federal valuation allowance (net) . . . . .	<u>52,710</u>	<u>—</u>	<u>6,496</u>
Income tax provision . . . . .	<u>\$48,062</u>	<u>\$ 2,918</u>	<u>\$ 895</u>

The significant components of the Company's deferred tax assets are as follows:

	<u>December 31,</u>	
	<u>2009</u>	<u>2008</u>
	(In thousands)	
Deferred tax assets:		
Net operating loss carryforwards . . . . .	\$ 95,800	\$ 56,037
Tax credits . . . . .	23,460	16,630
Intangible assets . . . . .	25,137	16,818
Stock based compensation . . . . .	18,507	14,876
Other . . . . .	<u>9,500</u>	<u>10,109</u>
Total deferred tax assets . . . . .	172,404	114,470
Valuation allowance . . . . .	<u>(171,386)</u>	<u>(64,547)</u>
Total deferred tax assets net of valuation allowance . . . . .	<u>1,018</u>	<u>49,923</u>
Deferred tax liabilities:		
Fixed assets . . . . .	\$ (1,018)	\$ (1,198)
Indefinite lived intangible assets . . . . .	(18,395)	—
Other . . . . .	<u>—</u>	<u>(494)</u>
Total deferred tax liabilities . . . . .	<u>(19,413)</u>	<u>(1,692)</u>
Net deferred tax (liabilities) assets . . . . .	<u>\$ (18,395)</u>	<u>\$ 48,231</u>

At December 31, 2009 a total of \$10.7 million of the deferred tax asset valuation allowance related to net operating loss carryforwards is associated with the exercise of non-qualified stock options. Such benefits, when realized, will be credited to additional paid-in capital.

During 2008, the Company reduced its net deferred tax asset to \$48.2 million which included a reduction of the net deferred tax asset by \$1.5 million related to the deferred tax provision and by \$0.7 million of other

**THE MEDICINES COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

activity recorded directly to equity including an adjustment to additional paid-in capital for the tax effect of option exercises and adjustments for unrealized gains on available for sale securities. The Company believed that it was more likely than not that the net deferred tax asset of \$48.2 million would be realized in future periods.

During 2009, the Company increased the valuation allowance associated with its net deferred tax assets to \$171.4 million (100% ) because it considered that future realization of these assets would not be more likely than not.

The Company will continue to evaluate the realizability of its deferred tax assets and liabilities on a periodic basis, and will adjust such amounts in light of changing facts and circumstances, including but not limited to future projections of taxable income, tax legislation, rulings by relevant tax authorities, the progress of ongoing tax audits, the regulatory approval of products currently under development, extension of the patent rights relating to Angiomax. If the Company further reduces the valuation allowance on deferred tax assets in future years, the Company would recognize a tax benefit.

In 1998 and 2002, the Company experienced a change in ownership as defined in Section 382 of the Internal Revenue Code. Section 382 can potentially limit a company's ability to use net operating losses, tax credits and other tax attributes in periods subsequent to a change in ownership. However, based on the market value of the Company at such dates, the Company believes that these ownership changes will not significantly impact its ability to use net operating losses or tax credits in the future to offset taxable income. On February 26, 2009 the Company acquired 100% of the stock of Targanta and became a successor to certain of its net operating loss and tax credit carryforwards. These tax attributes are also subject to a limitation under Internal Revenue Code Section 382 and the amounts combined with those of the Company in the table below have been reduced for such limitation.

At December 31, 2009, the Company has federal net operating loss carryforwards available to reduce taxable income, and federal research and development tax credit carryforwards available to reduce future tax liabilities, which expire approximately as follows:

<u>Year of Expiration</u>	<u>Federal Net Operating Loss Carryforwards</u>	<u>Federal Research and Development Tax Credit Carryforwards</u>
	(In thousands)	
2018 .....	\$ —	\$ 95
2019 .....	—	923
2020 .....	5,683	1,083
2021 .....	51,100	477
2022 .....	41,403	1,856
2023 .....	19,693	2,031
2024 .....	11	1,795
2025 .....	12,858	3,436
2026 .....	9,628	1,971
2027 .....	30,804	1,190
2028 .....	43,710	1,372
2029 .....	—	1,195
	<u>\$214,890</u>	<u>\$17,424</u>

At December 31, 2009 the Company has the following additional carryforwards: Alternative Minimum Tax Credits of \$2.3 million with no expiration date, state net operating losses of approximately \$124 million

**THE MEDICINES COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

expiring between 2010 and 2014 and foreign net operating losses of approximately \$53 million expiring between 2013 and 2028.

On January 1, 2007, the Company adopted FIN 48, which was later superseded by ASC 740, which clarifies the accounting for income taxes by prescribing the minimum threshold a tax position is required to meet before being recognized in the financial statements as well as guidance on de-recognition, measurement, classification and disclosure of tax positions. The Company reduced its deferred tax asset attributable to certain tax credits by approximately \$1.2 million in 2007 and \$0.2 million in 2008 to appropriately measure the amount of such deferred tax asset. No adjustment was made in 2009. The recognition of these tax benefits will impact the Company's effective income tax rate when recognized. The Company does not anticipate a significant change in its unrecognized tax benefits in the next twelve months. The Company is no longer subject to federal, state or foreign income tax audits for tax years prior to 2004, however such taxing authorities can review any net operating losses utilized by the Company in years subsequent to 2003. A reconciliation of the beginning and ending amount of gross unrecognized tax benefits is as follows:

	<u>Gross Unrecognized Tax Benefits</u> (In thousands)
Balance at January 1, 2008 . . . . .	\$1,214
Additions related to current year tax positions . . . . .	167
Additions for prior year tax positions . . . . .	—
Reductions for prior year tax positions . . . . .	—
Settlements . . . . .	<u>—</u>
Balance at December 31, 2008 . . . . .	1,381
Additions related to current year tax positions . . . . .	—
Additions for prior year tax positions . . . . .	—
Reductions for prior year tax positions . . . . .	—
Settlements . . . . .	<u>—</u>
Balance at December 31, 2009 . . . . .	<u>\$1,381</u>

The Company classifies interest and penalties related to unrecognized tax benefits in income tax expense. The Company has not accrued any interest or penalties as of December 31, 2009.

**14. Fair Value Measurements**

On January 1, 2008, the Company adopted the provisions of ASC 820-10, "Fair Value Measurements and Disclosures" (ASC 820-10) for financial assets and liabilities. As permitted by ASC 820-10, the Company elected to defer until January 1, 2009 the adoption of ASC 820-10 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis. ASC 820-10 provides a framework for measuring fair value under GAAP and requires expanded disclosures regarding fair value measurements. ASC 820-10 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820-10 also establishes a fair value hierarchy that requires an entity to maximize the

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

- Level 1** Quoted prices in active markets for identical assets or liabilities. The Company's Level 1 assets and liabilities consist of money market investments.
- Level 2** Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. The Company's Level 2 assets and liabilities consist of U.S. government agency and corporate debt securities.
- Level 3** Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. The Company's Level 3 assets and liabilities consist of the contingent purchase price associated with the Targanta acquisition (note 6). The fair value of the contingent purchase price was determined utilizing a probability weighted discounted financial model.

The following table sets forth the Company's assets and liabilities that were measured at fair value on a recurring basis at December 31, 2009 by level within the fair value hierarchy. As required by ASC 820-10, assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability:

<u>Assets and Liabilities</u>	<u>Quoted Prices in Active Markets for Identical Assets (Level 1)</u>	<u>Significant Other Observable Inputs (Level 2)</u>	<u>Significant Unobservable Inputs (Level 3)</u>	<u>Balance at December 31, 2009</u>
	(In thousands)			
Assets:				
Money market . . . . .	\$25,073	\$ —	\$ —	\$ 25,073
U.S. government agency . . . . .	—	103,965	—	103,965
Corporate debt securities . . . . .	<u>—</u>	<u>22,401</u>	<u>—</u>	<u>22,401</u>
Total assets at fair value . . . . .	\$25,073	\$126,366	\$ —	\$151,439
Liabilities:				
Contingent purchase price . . . . .	<u>\$ —</u>	<u>\$ —</u>	<u>\$23,667</u>	<u>\$ 23,667</u>
Total liabilities at fair value . . . . .	\$ —	\$ —	\$23,667	\$ 23,667

The changes in fair value of the Company's Level 3 contingent purchase price during the nine months ended December 31, 2009 were as follows:

	<u>Level 3</u>
	(In thousands)
Balance at December 31, 2008 . . . . .	\$ —
Contingent purchase price related to acquisition of Targanta . . . . .	23,181
Fair value adjustment to contingent purchase price included in net loss . . . . .	<u>486</u>
Balance at December 31, 2009 . . . . .	<u>\$23,667</u>

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**15. License Agreements**

*Angiomax*

In March 1997, the Company entered into an agreement with Biogen, Inc., a predecessor of Biogen Idec, for the license of the anticoagulant pharmaceutical bivalirudin, which the Company has developed as Angiomax. Under the terms of the agreement, the Company acquired exclusive worldwide rights to the technology, patents, trademarks, inventories and know-how related to Angiomax. In exchange for the license, the Company paid \$2.0 million on the closing date and is obligated to pay up to an additional \$8.0 million upon the first commercial sales of Angiomax for the treatment of acute myocardial infarction in the United States and Europe. In addition, the Company is obligated to pay royalties on sales of Angiomax and on any sublicense royalties on a country-by-country basis earned until the later of (1) 12 years after the date of the first commercial sales of the product in a country or (2) the date on which the product or its manufacture, use or sale is no longer covered by a valid claim of the licensed patent rights in such country. Under the terms of the agreement, the royalty rate due to Biogen Idec on sales increases with growth in annual sales of Angiomax. The agreement also stipulates that the Company use commercially reasonable efforts to meet certain milestones related to the development and commercialization of Angiomax, including expending at least \$20 million for certain development and commercialization activities, which the Company met in 1998. The license and rights under the agreement remain in force until the Company's obligation to pay royalties ceases. Either party may terminate the agreement for material breach by the other party, if the material breach is not cured within 90 days after written notice. In addition, the Company may terminate the agreement for any reason upon 90 days prior written notice. The Company recognized royalty expense under the agreement of \$77.4 million in 2009, \$53.6 million in 2008 and \$40.3 million in 2007 for Angiomax sales.

*Cleviprex*

The Company exclusively licensed Cleviprex in March 2003 from AstraZeneca for all countries other than Japan. In May 2006, the Company amended its license agreement with AstraZeneca to provide exclusive license rights in Japan in exchange for an upfront payment. The Company acquired this license after having studied Cleviprex under a study and exclusive option agreement with AstraZeneca that the Company entered into in March 2002. Under the terms of the agreement, the Company has the rights to the patents, trademarks, inventories and know-how related to Cleviprex. In exchange for the license, the Company paid \$1.0 million in 2003 upon entering into the license and agreed to pay up to an additional \$5.0 million upon reaching certain regulatory milestones, including a payment of \$1.5 million that was remitted in September 2007 after the FDA accepted the NDA for Cleviprex for the treatment of acute hypertension and a payment of \$1.5 million paid in the third quarter of 2008 upon the FDA's approval of Cleviprex. In addition, the Company will be obligated to pay royalties on a country-by-country basis on future annual sales of Cleviprex, and on any sublicense royalties earned, until the later of (1) the duration of the licensed patent rights which are necessary to manufacture, use or sell Cleviprex in a country or (2) ten years from the Company's first commercial sale of Cleviprex in such country. The licenses and rights under the agreement remain in force on a country-by-country basis until the Company ceases selling Cleviprex in such country or the agreement is otherwise terminated. The Company may terminate the agreement upon 30 days written notice, unless AstraZeneca, within 20 days of having received the Company's notice, requests that the Company enter into good faith discussions to redress its concerns. If the Company cannot reach a mutually agreeable solution with AstraZeneca within three months of the commencement of such discussions, the Company may then terminate the agreement upon 90 days written notice. Either party may terminate the agreement for material breach upon 60 days prior written notice, if the breach is not cured within such 60 days.



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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

*Cangrelor*

In December 2003, the Company acquired from AstraZeneca exclusive license rights to cangrelor for all countries other than Japan, China, Korea, Taiwan and Thailand. Under the terms of the agreement, the Company has the rights to the patents, trademarks, inventories and know-how related to cangrelor. In exchange for the license, in January 2004 the Company paid an upfront payment of \$1.5 million upon entering into the license and agreed to make additional milestone payments of up to \$4.5 million in the aggregate upon reaching certain potential regulatory milestones. To date, the Company has paid AstraZeneca approximately \$1.7 million pursuant to the license agreement, which includes the \$1.5 million upfront payment and \$0.2 million for the transfer of technology in 2004. Under the terms of the license agreement, the Company will be obligated to pay royalties ranging from 10% to 20% on a country-by-country basis on future annual sales of cangrelor, and on any sublicense royalties earned, until the later of (1) the duration of the licensed patent rights which are necessary to manufacture, use or sell cangrelor in a country or (2) ten years from the Company's first commercial sale of cangrelor in such country. The licenses and rights under the agreement remain in force on a country-by-country basis until the Company ceases selling cangrelor in such country or the agreement is otherwise terminated. The Company may terminate the agreement upon 30 days' written notice, unless AstraZeneca, within 20 days of having received the Company's notice, requests that the Company enter into good faith discussions to redress the Company's concerns. If the Company cannot reach a mutually agreeable solution with AstraZeneca within three months of the commencement of such discussions, the Company may then terminate the agreement upon 90 days' written notice. Either party may terminate the agreement for material breach upon 60 days' prior written notice if the breach is not cured within such 60 days.

*ApoA-I Milano*

In December 2009, the Company entered into an agreement with Pfizer Inc. (Pfizer) with respect to the compound designated by Pfizer as ETC-216 (ETC-216), a variant of ApoA-I Milano, a naturally occurring variant of a protein found in human high-density lipoprotein. Pursuant to the agreement, Pfizer granted the Company an exclusive, worldwide, royalty-bearing license under specified Pfizer patents, patent applications and know-how to develop, manufacture and commercialize products containing ETC-216 and improvements to ETC-216 (collectively, the Products). The Company may sublicense the intellectual property to third parties, provided that it has complied with Pfizer's right of first negotiation and, in the case of sublicenses, to unaffiliated third parties in certain countries, provided that it has first obtained Pfizer's consent. The Company, itself or through its affiliates or sublicensees, has agreed to use commercially reasonable efforts to develop at least one Product and to commercialize any approved Products.

Under the agreement, the Company paid Pfizer an upfront payment of \$10,000,000 and upon the achievement of clinical, regulatory and sales milestones will pay up to an aggregate of \$410,000,000. The Company has also agreed to make royalty payments to Pfizer on the sale of the Products by the Company, its affiliates or sublicensees. The royalties are payable, on a Product-by-Product and country-by-country basis, until the latest of the expiration of the last patent or patent application covering the Product, the expiration of any market exclusivity, and a specified period of time after first commercial sale of the Product. The Company has also agreed to pay Pfizer a portion of the consideration received by the Company or its affiliates in connection with sublicenses. The Company also paid \$7.5 million to third parties in connection with the license and agreed to make additional payments to them of up to \$12.0 million in the aggregate upon the achievement of specified development milestones and continuing payments on sales of ApoA-I Milano.

The Company has agreed to indemnify Pfizer against third party claims arising from (a) the development and commercialization of the Products by the Company, its affiliates, subcontractors or sublicensees, (b) the negligence or wrongful intentional acts or omissions of the Company, its affiliates, subcontractors or sublicensees, (c) a breach of the agreement by the Company, or (d) claims by a Brewer/Matin Party (as

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defined in the agreement with Pfizer) resulting from the agreement or any agreement or arrangement between the Company and a Brewer/Matin Party.

The agreement will expire upon expiration of the Company's obligation to make royalty payments. Each party may terminate the agreement if (a) the other party breaches its material obligations under the agreement and fails to cure such breach during a specified period of time, (b) the other party become insolvent or bankrupt, or (c) the other party is subject to a force majeure event for a specified period of time. Pfizer may also terminate the agreement if the Company provides written notice to Pfizer that the Company intends to permanently abandon the development, manufacture and commercialization of the Products or if the Company otherwise ceases, for a specified period of time, to use commercially reasonable efforts to develop, manufacture and commercialize, as applicable, at least one Product. The Company may terminate the agreement in its entirety, or on a Product-by-Product basis, at any time and for any reason upon prior written notice.

Upon termination of the agreement, the licenses to the Company terminate. If Pfizer terminates the agreement due to the Company's uncured breach, bankruptcy, force majeure event, abandonment of the Products or ceasing to use commercially reasonable efforts to develop and commercialize at least one Product, or if the Company terminates the agreement for convenience, the Company will grant Pfizer a sublicenseable, royalty-free, perpetual license under any intellectual property licenseable by the Company that arose from the Company's development or commercialization of the terminated Products, to develop, manufacture and commercialize the terminated Products. This license will be non-exclusive with respect to trademarks and exclusive with respect to other intellectual property.

**16. Manufacturing Agreements**

*Lonza Braine S.A. (formerly UCB Bioproducts)*

In December 1999, the Company entered into a commercial supply agreement with Lonza Braine S.A. (formerly UCB Bioproducts S.A) for the development and supply of the Angiomax bulk drug substance. Under the terms of the commercial supply agreement, Lonza Braine completed development of a modified production process known as the Chemilog process and filed an amendment in 2001 to its drug master file for regulatory approval of the Chemilog process by the FDA. The Chemilog process was approved by the FDA in May 2003. The Company has agreed to purchase a substantial portion of its Angiomax bulk drug product manufactured using the Chemilog process from Lonza Braine at agreed upon prices for a period ending in September 2011. Following the expiration of the agreement, which automatically renews for consecutive three-year periods unless either party provides notice of non-renewal within one year prior to the expiration of the initial term or any renewal term, or if the Company terminates the agreement prior to its expiration, Lonza Braine has agreed to transfer the development technology to the Company. If the Company engages a third party to manufacture Angiomax using this technology prior to bivalirudin becoming a generic drug in the United States, the Company will be obligated to pay Lonza Braine a royalty based on the amount paid by the Company to the third-party manufacturer. The Company may only terminate the agreement prior to its expiration in the event of a material breach by Lonza Braine. During 2009, 2008 and 2007 the Company recorded \$23.3 million, \$8.6 million and \$10.4 million, respectively, in costs related to Lonza Braine's production of Angiomax bulk drug substance.

*Ben Venue Laboratories, Inc.*

On October 23, 1997, the Company entered into a master agreement with Ben Venue Laboratories, Inc. (Ben Venue) for the manufacture of the finished drug product of Angiomax. Ben Venue conducts the fill-finish of Angiomax drug product in the United States for the Company through purchase order arrangements agreed upon by the parties and governed by the master agreement.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**17. Commitments and Contingencies**

The Company's long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. These include commitments related to purchases of inventory of the Company's products, research and development service agreements, operating leases and selling, general and administrative obligations, increases to the Company's restricted cash in connection with its new principal office space in Parsippany, New Jersey, and royalty and milestone payments due.

Future estimated contractual obligations as of December 31, 2009 are:

<u>Contractual Obligations</u>	<u>2010</u>	<u>2011</u>	<u>2012</u>	<u>2013</u>	<u>2014</u>	<u>Later Years</u>	<u>Total</u>
	(In thousands)						
Inventory related commitments . . . . .	\$27,897	\$19,469	\$ 600	\$ —	\$ —	\$ —	\$ 47,966
Research and development . . . . .	17,880	4,754	1,034	768	—	—	24,436
Operating leases . . . . .	6,997	7,446	6,184	5,796	4,662	38,102	69,187
Selling, general and administrative . . .	5,246	504	—	—	—	—	5,750
Unrecognized tax benefits . . . . .	—	167	—	—	—	—	167
Total contractual obligations . . . . .	<u>\$58,020</u>	<u>\$32,340</u>	<u>\$7,818</u>	<u>\$6,564</u>	<u>\$4,662</u>	<u>\$38,102</u>	<u>\$147,506</u>

All of the inventory related commitments included above are non-cancellable. Included within the inventory related commitments above are purchase commitments to Lonza Braine totaling \$26.1 million for 2010 and \$19.1 million for 2011 for Angiomax bulk drug substance. Of the total estimated contractual obligations for research and development and selling, general and administrative activities, \$3.6 million is non-cancellable.

In January 2009, the Company moved its principal offices to a new office building in Parsippany, New Jersey. The lease covering the new office building covers 173,146 square feet and expires January 2024. In connection with the move, the Company vacated its previous office space in Parsippany. The lease for the Company's old office facility expires January 2013. In the second half of 2009, the Company sublet its old office space to two companies. The first sublease, for the second floor of the Company's old office space, expires in March 2011, subject to renewal by the subtenant for three period(s) of six months each and thereafter for one period of four months, and the second sublease, covering the first floor of the Company's previous office space, expires in January 2013. Additionally, certain other costs such as leasing commissions and legal fees will be expensed as incurred in conjunction with the sublease of the vacated office space.

Approximately 85% of the total operating lease commitments above relate to the Company's new office building. Also included in total operating lease commitments are automobile leases, computer leases, the operating lease from the Company's previous office space and other property leases that it entered into while expanding the Company's European infrastructure.

In addition, the Company leases offices in Waltham, Massachusetts; Milton Park, Abingdon, United Kingdom; Zurich, Switzerland; Paris, France; Rome Italy; Munich, Germany; Leipzig, Germany; and Montreal, Canada. Rent expense for these offices was approximately \$7.5 million in 2009, \$2.2 million in 2008 and \$1.6 million in 2007.

In addition to the amounts shown in the above table, and royalty payments the Company is contractually obligated to make potential future success-based development, regulatory and commercial milestone payments in conjunction with collaborative agreements or acquisitions it has entered into with third-parties.

These payments are contingent upon the occurrence of certain future events and, given the nature of these events, it is unclear when, if ever, the Company may be required to pay such amounts. These contingent payments have not been included in the table above or recorded on the Company's consolidated balance sheets. Further, the timing of any future payment is not reasonable estimable. As such, obligations related to

## THE MEDICINES COMPANY

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

the acquisition of Targanta which occurred in February 2009, include contingent cash payments up to approximately \$90.4 million that would be owed to former Targanta shareholders under the Company's merger agreement with Targanta, are not included in the above.

#### *Litigation*

From time to time, the Company is party to legal proceedings in the course of its business in addition to those described below. The Company does not, however, expect such other legal proceedings to have a material adverse effect on the Company's business, financial condition or results of operations

#### *Teva Parenteral Medicines, Inc.*

In September 2009, the Company was notified that Teva Parenteral Medicines, Inc. had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 patent. The '727 patent was issued on September 1, 2009 and relates to a more consistent and improved Angiomax drug product. The '727 patent expires on July 27, 2028. On October 8, 2009, the Company filed suit against Teva Parenteral Medicines, Inc., Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively, Teva) in the U.S. District Court for the District of Delaware for infringement of the '727 patent. On October 29, 2009, Teva filed an answer denying infringement and alleging affirmative defenses of non-infringement and invalidity. On October 21, 2009, the case was reassigned in lieu of a vacant judgeship to the U.S. District Court for the Eastern District of Pennsylvania. The court has yet to set a schedule in the case.

On October 08, 2009, the Company was issued the '343 patent, which relates to a more consistent and improved Angiomax drug product made by processes described in the patent. On January 4, 2010, the Company filed suit against Teva Parenteral Medicines, Inc. and its related parent entities in the U.S. District Court for the District of Delaware for infringement of the '343 patent. The case was assigned to the same judge in the Eastern District of Pennsylvania as the '727 case above.

#### *Pliva Hrvatska d.o.o.*

In September 2009, the Company was notified that Pliva Hrvatska d.o.o. had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 patent. On October 8, 2009, the Company filed suit against Pliva Hrvatska d.o.o., Pliva d.d., Barr Laboratories, Inc., Barr Pharmaceuticals, Inc., Barr Pharmaceuticals, LLC, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively, Pliva) in the U.S. District Court for the District of Delaware for infringement of the '727 patent. On October 28, 2009, Pliva filed an answer denying infringement and alleging affirmative defenses of non-infringement and invalidity. On October 21, 2009, the case was reassigned in lieu of a vacant judgeship to the U.S. District Court for the Eastern District of Pennsylvania. The court has yet to set a schedule in the case.

On October 08, 2009, the Company was issued the '343 patent, which relates to a more consistent and improved Angiomax drug product made by processes described in the patent. On January 4, 2010, the Company filed suit against Pliva Hrvatska d.o.o. and its related parent entities in the U.S. District Court for the District of Delaware for infringement of the '343 patent. The case was assigned to the same Judge in the Eastern District of Pennsylvania as the '727 case above.

#### *APP Pharmaceuticals, LLC*

In September 2009, the Company was notified that APP Pharmaceuticals, LLC had submitted an ANDA seeking permission to market its generic version of Angiomax prior to the expiration of the '727 patent. On October 8, 2009, the Company filed suit against APP Pharmaceuticals, LLC and APP Pharmaceuticals, Inc.

**THE MEDICINES COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

(collectively, APP) in the U.S. District Court for the District of Delaware for infringement of the '727 patent. APP requested and a Stipulation has been filed extending APP's time to answer until December 9, 2009. On October 21, 2009, the case was reassigned in lieu of a vacant judgeship to the U.S. District Court for the Eastern District of Pennsylvania. The court has yet to set a schedule in the case. An amended complaint was filed on February 5, 2010. APP's answer denied infringement and raised counterclaims of invalidity, non-infringement and a request to delist the '727 patent from the Orange Book. On March 1, 2010 the Company filed a reply denying the counterclaims raised by APP. The court has yet to set a schedule in the case.

*Contingencies*

The U.S. Patent and Trademark Office (PTO) rejected the application under the Hatch-Waxman Act for an extension of the term of U.S. Patent No. 5,196,404 (the '404 patent), the principal U.S. patent that covers Angiomax (the patent extension filing), beyond March 23, 2010 because in its view the application was not timely filed. The Company has entered into agreements with the law firms involved in the patent extension filing that suspend the statute of limitations on any claims against them for failing to make a timely filing. The Company has entered into a similar agreement with Biogen Idec, one of its licensors for Angiomax, relating to any claims, including claims for damages and/or license termination, that Biogen Idec may bring relating to the patent extension filing. Such claims by Biogen Idec could have a material adverse effect on the Company's financial condition, results of operations, liquidity or business. In the third quarter of 2009, the Company initiated discussions, which are still ongoing, with the law firms involved in the patent extension filing and are currently in related discussions with Biogen Idec and HRI with respect to the possible resolution of potential claims among the parties.

**18. Employee Benefit Plan**

The Company has an employee savings and retirement plan which is qualified under Section 401(k) of the Internal Revenue Code. The Company's employees may elect to reduce their current compensation up to the statutorily prescribed limit and have the amount of such reduction contributed to the 401(k) plan. The Company may make matching or additional contributions to the 401(k) plan in amounts to be determined annually by the Board of Directors. The Company has not made any matching or additional contributions to date.

**19. Selected Quarterly Financial Data (Unaudited)**

The following table presents selected quarterly financial data for the years ended December 31, 2009 and 2008.

	<b>Three Months Ended</b>							
	<b>Mar. 31, 2009</b>	<b>June 30, 2009</b>	<b>Sept. 30, 2009</b>	<b>Dec. 31, 2009</b>	<b>Mar. 31, 2008</b>	<b>June 30, 2008</b>	<b>Sept. 30, 2008</b>	<b>Dec. 31, 2008</b>
	(In thousands, except per share data)							
Net revenue . . . . .	\$99,217	\$104,175	\$98,789	\$102,060	\$79,427	\$86,731	\$ 88,126	\$93,873
Cost of revenue . . . . .	28,297	30,353	28,308	31,190	19,092	21,939	22,089	25,235
Total operating expenses . . . . .	78,031	67,694	69,822	95,894	54,013	58,570	86,939	71,101
Net income/(loss) . . . . .	(3,348)	3,811	(3,197)	(73,494)	4,853	4,056	(13,217)	(4,196)
Basic net income/(loss) per common share . . . . .	\$ (0.06)	\$ 0.07	\$ (0.06)	\$ (1.40)	\$ 0.09	\$ 0.08	\$ (0.25)	\$ (0.08)
Diluted net income/(loss) per common share . . . . .	\$ (0.06)	\$ 0.07	\$ (0.06)	\$ (1.40)	\$ 0.09	\$ 0.08	\$ (0.25)	\$ (0.08)

**THE MEDICINES COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

**20. Segment and Geographic Information**

The Company manages its business and operations as one segment and is focused on advancing the treatment of critical care patients through the delivery of innovative, cost-effective medicines to the worldwide hospital marketplace. Revenues reported to date are derived primarily from the sales of Angiomax in the United States.

The geographic segment information provided below is classified based on the major geographic regions in which the Company operates.

	<u>2009</u>	<u>Years Ended December 31,</u>				
		<u>2008</u>		<u>2007</u>		
					(In thousands)	
Net revenue:						
United States .....	\$385,939	95.5%	\$334,582	96.1%	\$254,975	99.0%
Europe .....	13,908	3.4%	9,051	2.6%	(268)	(0.1)%
Other .....	<u>4,394</u>	1.1%	<u>4,524</u>	1.3%	<u>2,827</u>	1.1%
Total net revenue .....	<u>404,241</u>		<u>348,157</u>		<u>257,534</u>	

	<u>Years Ended December 31,</u>				
	<u>2009</u>	<u>2008</u>			<u>2007</u>
		(In thousands)			
Long-lived assets:					
United States .....		\$122,968	98.4%	\$47,308	96.7%
Europe .....		1,684	1.3%	1,609	3.3%
Other .....		<u>353</u>	0.3%	<u>—</u>	—%
Total long-lived assets .....		<u>\$125,005</u>		<u>\$48,917</u>	

**21. Subsequent Events**

*Workforce Reductions*

On January 7, 2010 and February 9, 2010, the Company commenced two separate workforce reductions to improve efficiencies and better align its costs and structure for the future. As a result of the first workforce reduction, the Company reduced its office-based personnel by 30 employees. The second workforce reduction resulted in a reduction of 42 primarily field-based employees. Upon signing release agreements, affected employees received reduction payments, earned 2009 bonuses, fully paid health care coverage for six months and outplacement services. The Company completed the workforce reductions in February 2010.

The Company expects to record, in the aggregate, charges of approximately \$7.0 million associated with these workforce reductions, which will be recognized in the first quarter of 2010. Substantially all of these charges are expected to represent cash expenditures. The Company expects to realize estimated annualized cost savings from the workforce reductions in the range of \$14.5 to \$16.5 million starting in the first quarter of 2010.

*Litigation*

On January 27, 2010, the Company filed a complaint in the U.S. District Court for the Eastern District of Virginia against the PTO, the FDA, the U.S. Department of Health and Human Services, et al. seeking to set aside the denial of its application pursuant to the Hatch-Waxman Act to extend the term of the '404 patent. In

**THE MEDICINES COMPANY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

the complaint, the Company primarily alleges that the PTO and FDA each misinterpreted the filing deadlines in the Hatch-Waxman Act when they rendered their respective determinations that the Company's application for extension of the term of the '404 patent was not timely filed. As a result, the Company is asking the court to grant relief including to vacate and set aside the PTO's and FDA's determinations regarding the timeliness of its application for patent term extension and to order the PTO to extend the term of the '404 patent for the full period required under the Hatch-Waxman Act. On March 10, 2010, the court conducted a hearing on the parties' cross motions for summary judgment.

**Schedule II**

**Valuation and Qualifying Accounts  
Year ended December 31, 2009, 2008 and 2007**

	<u>Balance at Beginning of Period</u>	<u>(Credit) Charged to Costs and Expenses(1)</u>	<u>Other Charges (Deductions)(2)</u>	<u>Balance at End of Period</u>
<b>2009</b>				
Allowances for chargebacks, cash discounts and doubtful accounts .....	\$1,916	\$29,678	\$(25,232)	\$6,362
<b>2008</b>				
Allowances for chargebacks, cash discounts and doubtful accounts .....	\$1,192	\$15,149	\$(14,425)	\$1,916
<b>2007</b>				
Allowances for chargebacks, cash discounts and doubtful accounts .....	\$ 800	\$10,024	\$ (9,632)	\$1,192

(1) amounts presented herein were charged to and reduced revenues

(2) represents actual cash discounts, chargeback credits and other deductions



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## INDEX TO EXHIBITS

<u>Number</u>	<u>Description</u>
2.1†	Sale and Purchase Agreement, dated August 4, 2008, between The Medicines Company (Leipzig) GmbH and Curacyte AG (filed as Exhibit 2.1 of the registrant's current report on Form 8-K/A, filed on November 10, 2008)
2.2	Agreement and Plan of Merger among the registrant, Boxford Subsidiary Corporation, and Targanta Therapeutics Corporation, dated as of January 12, 2009 (filed as Exhibit 2.1 of the registrant's current report on Form 8-K, filed on January 14, 2009)
2.3†	Amendment to Sale and Purchase Agreement dated December 14, 2009 between The Medicines Company (Leipzig) GmbH and Curacyte AG
3.1	Third Amended and Restated Certificate of Incorporation of the registrant, as amended (filed as Exhibit 4.1 to the Amendment No. 1 to the registrant's registration statement on Form 8-A/A, filed July 14, 2005)
3.2	Amended and Restated By-laws of the registrant, as amended (filed as Exhibit 3.2 to the registrant's annual report on Form 10-K for the year ended December 31, 2007)
10.1	Amended and Restated Registration Rights Agreement, dated as of August 12, 1998, as amended, by and among the registrant and the other parties thereto (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2002)
10.2	Lease for 8 Campus Drive dated September 30, 2002 by and between Sylvan/Campus Realty L.L.C. and the registrant, as amended by the First Amendment and Second Amendment, (filed as Exhibit 10.15 to the registrant's annual report on Form 10-K for the year ended December 31, 2003)
10.3	Third Amendment to Lease for 8 Campus Drive dated December 30, 2004 by and between Sylvan/Campus Realty L.L.C. and the registrant (filed as Exhibit 10.18 to the registrant's annual report on Form 10-K for the year ended December 31, 2004)
10.4	Lease for 8 Sylvan Way, Parsippany, NJ dated October 11, 2007 by and between 8 Sylvan Way, LLC and the registrant (filed as Exhibit 10.32 to the registrant's annual report on Form 10-K for the year ended December 31, 2007)
10.5	Amendment to Lease for 8 Sylvan Way, Parsippany, NJ dated October 11, 2007 by and between 8 Sylvan Way, LLC and the registrant (filed as Exhibit 10.40 to the registrant's annual report on Form 10-K for the year ended December 31, 2008)
10.6*	Employment agreement dated September 5, 1996 by and between the registrant and Clive Meanwell (filed as Exhibit 10.12 to the registration statement on Form S-1 filed on May 19, 2000 (registration no. 333-37404))
10.7*	Letter Agreement dated December 1, 2004 by and between the registrant and John Kelley (filed as Exhibit 10.25 to the registrant's annual report on Form 10-K for the year ended December 31, 2004)
10.8*	Letter Agreement dated March 2, 2006 by and between the registrant and Glenn P. Sblendorio, (filed as Exhibit 10.23 to the registrant's annual report on Form 10-K for the year ended December 31, 2005)
10.9*	Severance Agreement, dated February 17, 2009 by and between Catharine Newberry and the registrant (filed as Exhibit 10.42 to the registrant's annual report on Form 10-K for the year ended December 31, 2008)
10.10*	Severance Agreement, dated October 22, 2009 by and between John Kelley and the registrant (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2009)
10.11*	Form of Amended and Restated Management Severance Agreement by and between the registrant and each of Clive Meanwell and Glenn Sblendorio (filed as Exhibit 10.24 to the registrant's annual report on Form 10-K for the year ended December 31, 2008)
10.12*	Form of Amended and Restated Management Severance Agreement by and between the registrant and each of Paul Antinori, William O'Connor and Leslie Rohrbacker (filed as Exhibit 10.25 to the registrant's annual report on Form 10-K for the year ended December 31, 2008)
10.13*	Form of Lock-Up Agreement dated as of December 23, 2005 by and between the registrant and each of its executive officers and directors (filed as Exhibit 10.27 to the registrant's annual report on Form 10-K for the year ended December 31, 2005)

<u>Number</u>	<u>Description</u>
10.14*	Summary of Board of Director Compensation (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2007)
10.15*	1998 Stock Incentive Plan, as amended (filed as Exhibit 10.1 to the registration statement on Form S-1 filed on May 19, 2000 (registration no. 333-37404))
10.16*	Form of stock option agreement under 1998 Stock Incentive Plan (filed as Exhibit 10.3 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2004)
10.17*	2000 Employee Stock Purchase Plan, as amended (filed as Exhibit 10.1 of the registrant's registration statement on Form S-8, filed on September 1, 2009)
10.18*	2000 Outside Director Stock Option Plan, as amended (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2003)
10.19	2001 Non-Officer, Non-Director Employee Stock Incentive Plan (filed as Exhibit 99.1 to the registration statement on Form S-8 filed December 5, 2001 (registration no. 333-74612))
10.20*	Amended and Restated 2004 Stock Incentive Plan (filed as Exhibit 99.1 to the registrant's registration statement on Form S-8, dated July 3, 2008)
10.21*	Form of stock option agreement under 2004 Stock Incentive Plan (filed as Exhibit 10.22 to the registrant's annual report on Form 10-K for the year ended December 31, 2004)
10.22*	Form of restricted stock agreement under 2004 Stock Incentive Plan (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2006)
10.23*	2007 Equity Inducement Plan (filed as Exhibit 10.1 to the registration statement on Form S-8 filed January 11, 2008 (registration no. 333-148602))
10.24*	Form of stock option agreement under 2007 Equity Inducement Plan (filed as Exhibit 10.34 to the registrant's annual report on Form 10-K for the year ended December 31, 2007)
10.25*	Form of restricted stock agreement under 2007 Equity Inducement Plan (filed as Exhibit 10.35 to the registrant's annual report on Form 10-K for the year ended December 31, 2007)
10.26*	2009 Equity Inducement Plan (filed as Exhibit 10.1 to the registration statement on Form S-8 filed February 24, 2009 (registration number 333-157499))
10.27*	Form of stock option agreement under 2009 Equity Inducement Plan (filed as Exhibit 10.2 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2009)
10.28*	Form of stock option agreement for employees in Italy under 2009 Equity Inducement Plan (filed as Exhibit 10.3 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2009)
10.29*	Form of restricted stock agreement under 2009 Equity Inducement Plan (filed as Exhibit 10.4 to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2009)
10.30*	Summary of Annual Cash Bonus Plan (filed as Exhibit 10.2 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2008)
10.31*	Summary of Performance Measures under the registrant's Annual Cash Bonus Plan (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2009)
10.32†	License Agreement, dated as of June 6, 1990, by and between Biogen, Inc. and Health Research, Inc., as assigned to the registrant (filed as Exhibit 10.6 to the registration statement on Form S-1 filed on May 19, 2000 (registration no. 333-37404))
10.33†	License Agreement dated March 21, 1997, by and between the registrant and Biogen, Inc. (filed as Exhibit 10.7 to the registration statement on Form S-1 filed on May 19, 2000 (registration no. 333-37404))
10.34†	License Agreement effective as of March 28, 2003 by and between AstraZeneca AB and the registrant (filed as Exhibit 10.17 to the registrant's annual report on Form 10-K for the year ended December 31, 2003)
10.35†	Amendment No. 1 to License Agreement dated April 25, 2006 by and between AstraZeneca AB (filed as Exhibit 10.1 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2006)
10.36	Amendment No. 2 to License Agreement, dated October 22, 2008 by and between the registrant and AstraZeneca AB (filed as Exhibit 10.38 to the registrant's annual report on Form 10-K for the year ended December 31, 2008)

<u>Number</u>	<u>Description</u>
10.37†	License Agreement dated as of December 18, 2003 by and between AstraZeneca AB and the registrant (filed as Exhibit 10.18 to the registrant's annual report on Form 10-K for the year ended December 31, 2003)
10.38†	Amendment to License Agreement dated July 6, 2007 between AstraZeneca AB and the registrant (filed as Exhibit 10.4 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2007)
10.39	License Agreement, dated December 23, 2005 by and between Targanta Therapeutics Corporation (as successor to InterMune, Inc.) and Eli Lilly and Company (filed as Exhibit 10.11 to Targanta's registration statement on Form S-1 (registration no. 333-142842), as amended, originally filed with the SEC on May 11, 2007)
10.40	Contingent Payment Rights Agreement dated February 25, 2009 between the registrant and American Stock Transfer & Trust Company (filed as Exhibit 99.1 of the registrant's current report on Form 8-K, filed on March 2, 2009)
10.41†	License Agreement dated as of December 18, 2009 between the registrant and Pfizer Inc.
10.42†	Consent and Release Agreement dated as of December 18, 2009 between the registrant and Washington Cardiovascular Associates, LLC, HDLT LLC, H. Bryan Brewer, Silvia Santamarina-Fojo and Michael Matin
10.43†	Chemilog Development and Supply Agreement, dated as of December 20, 1999, by and between the registrant and UCB Bioproducts S.A. (filed as Exhibit 10.5 to the registration statement on Form S-1 filed on May 19, 2000 (registration no. 333-37404))
10.44†	Amended and Restated Distribution Agreement dated February 28, 2007 between the registrant and Integrated Commercialization Solutions, Inc. (filed as Exhibit 10.2 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2009)
10.45†	Amendment No. 1 to Amended and Restated Distribution Agreement dated November 7, 2007 between the registrant and Integrated Commercialization Solutions, Inc. (filed as Exhibit 10.3 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2009)
10.46†	Amendment No. 2 to Amended and Restated Distribution Agreement dated October 1, 2008 between the registrant and Integrated Commercialization Solutions, Inc. (filed as Exhibit 10.4 to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2009)
10.47†	Amendment No 3 to the Amended and Restated Distribution Agreement dated August 12, 2009 between the registrant and Integrated Commercialization Solutions, Inc. (filed as Exhibit 10.2 to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2009)
21	Subsidiaries of the registrant
23	Consent of Ernst & Young LLP, Independent Registered Accounting Firm
31.1	Chief Executive Officer — Certification pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Chief Financial Officer — Certification pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Chief Executive Officer — Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Chief Financial Officer — Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

\* Management contract or compensatory plan or arrangement filed as an exhibit to this form pursuant to Items 15(a) and 15(c) of Form 10-K

† Confidential treatment requested as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission Unless otherwise indicated, the exhibits incorporated herein by reference were filed under Commission file number 000-31191.

## CERTIFICATIONS

I, Clive A. Meanwell, certify that:

1. I have reviewed this Annual Report on Form 10-K of The Medicines Company;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Clive A. Meanwell

Clive A. Meanwell  
Chairman and Chief Executive Officer

Dated: March 16, 2010

## CERTIFICATIONS

I, Glenn P. Sblendorio, certify that:

1. I have reviewed this Annual Report on Form 10-K of The Medicines Company;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Glenn P. Sblendorio

Glenn P. Sblendorio

Executive Vice President and Chief Financial Officer

Dated: March 16, 2010

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of The Medicines Company (the "Company") for the period ended December 31, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Clive A. Meanwell, Chairman and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Clive A. Meanwell \_\_\_\_\_

Clive A. Meanwell  
Chairman and Chief Executive Officer

Dated: March 16, 2010

A signed original of this written statement required by Section 906 has been provided to The Medicines Company and will be retained by The Medicines Company and furnished to the SEC or its staff upon request

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of The Medicines Company (the "Company") for the period ended December 31, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Glenn P. Sblendorio, Executive Vice President and Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Glenn P. Sblendorio

Glenn P. Sblendorio  
Executive Vice President and Chief Financial  
Officer

Dated: March 16, 2010

A signed original of this written statement required by Section 906 has been provided to The Medicines Company and will be retained by The Medicines Company and furnished to the SEC or its staff upon request



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